

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION

- - -

4 IN RE: NATIONAL : HON. DAN A.
5 PRESCRIPTION OPIATE : POLSTER
6 LITIGATION :
7 :
8 APPLIES TO ALL CASES : NO.
9 : 1:17-MD-2804
10 :
11 :

- HIGHLY CONFIDENTIAL -

SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

VOLUME I

- - -

January 22, 2019

- - -

15 Videotaped deposition of
16 MICHELE R. DEMPSEY, taken pursuant to
17 notice, was held at the law offices of
18 Drinker Biddle & Reath, 105 College Road
19 East, Princeton, New Jersey, beginning at
20 9:12 a.m., on the above date, before
21 Michelle L. Gray, a Registered
22 Professional Reporter, Certified
23 Shorthand Reporter, Certified Realtime
24 Reporter, and Notary Public.

- - -

21 GOLKOW LITIGATION SERVICES
22 877.370.3377 ph | 917.591.5672 fax
23 deps@golkow.com
24

1 APPEARANCES:
2

THE LANIER FIRM

3 BY: EVAN M. JANUSH, ESQ.

IAN S. MILLICAN, ESQ.

4 126 East 56th Street

6th Floor

5 New York, New York 10022

(212) 421-2800

6 evan.janush@lanierlawfirm.com

ian.millican@lanierlawfirm.com

7 Representing the Plaintiffs
8

O'MELVENY & MYERS, LLP

9 BY: JEFFREY A. BARKER, ESQ.

610 Newport Center Drive

10 Newport Beach, California 92660

(949) 823-79623

11 Jbarker@omm.com

12 - and -

13 O'MELVENY & MYERS, LLP

BY: EMILIE K. WINCKEL, ESQ.

14 1625 Eye Street, NW

Washington, D.C. 20006

15 (202) 383-5300

Ewinckel@omm.com

16 Representing the Defendants, Janssen

and Johnson & Johnson and the

17 Witness
18

PIETRAGALLO GORDON ALFANO BOSICK &

19 RASPANTI, LLP

BY: ELISA M. BOODY, ESQ.

20 1818 Market Street, Suite 3402

Philadelphia, Pennsylvania 19103

21 (215) 320-6200

emb@pietragallos.com

22 Representing the Defendant, Cardinal

Health
23
24

1 TELEPHONIC APPEARANCES:

2 REED SMITH, LLP

3 BY: SARAH B. JOHANSEN, ESQ.
355 South Grand Avenue, Suite 2900
4 Los Angeles, California 90071
(213) 457-8135
5 sjohansen@reedsmith.com
Representing the Defendant,
6 AmerisourceBergen
7

8 HUGHES HUBBARD & REED, LLP

9 BY: TINA M. SCHAEFER, ESQ.
2345 Grand Boulevard
Kansas City, Missouri 64108
(816) 709-4159
10 tina.schaefer@hugheshubbard.com
Representing the Defendant, UCB,
11 Inc.
12

13 ARNOLD & PORTER KAYE SCHOLER, LLP

14 BY: KAREN RIGBERG, ESQ.
777 Figueroa Street, 44th Floor
Los Angeles, California 90017
(213) 243-4000
15 karen.rigberg@arnoldporter.com
Representing the Defendants, Endo
16 Health Solutions; Endo
Pharmaceuticals, Inc.; Par
17 Pharmaceutical Companies, Inc. f/k/a
Par Pharmaceutical Holdings, Inc.
18

19 JONES DAY

20 BY: NICOLE LANGSTON, ESQ.
77 West Wacker Drive
Chicago, Illinois 60601
21 (312) 269-4113
Nlangston@jonesday.com
22 Representing the Defendant, Walmart
23
24

1 APPEARANCES: (Cont'd.)

2

3 ALSO PRESENT:

4

5 VIDEOTAPE TECHNICIAN:

6 Henry Marte

7

Sofia McDonald - Law Clerk

8 (Ropes & Gray)

9

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I N D E X
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Testimony of:

MICHELE R. DEMPSEY

By Mr. Janush

12

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2

THE VIDEOGRAPHER: We are

3

now on the record. My name is

4

Henry Marte, videographer with

5

Golkow Litigation Services.

6

Today's date is

7

January 22nd, 2019, and the time

8

on the monitor is 9:12 a.m.

9

This videotaped deposition

10

is being held in Princeton, New

11

Jersey, in the matter of National

12

Prescription Opiate Litigation.

13

The deponent today is

14

Michele Dempsey. All appearances

15

are noted on the stenographic

16

record.

17

Will the court reporter

18

please administer the oath to the

19

witness.

20

- - -

21

... MICHELE R. DEMPSEY,

22

having been first duly sworn, was

23

examined and testified as follows:

24

- - -

1

EXAMINATION

2

- - -

3

BY MR. JANUSH:

4

Q. Hi, Ms. Dempsey. How are

5

you this morning?

6

A. Good. Thank you.

7

Q. My name is Evan Janush. I

8

had an opportunity to introduce myself to

9

you at the hotel just moments ago. It's

10

been a pleasure to meet you.

11

I represent the plaintiffs

12

in this case taking this deposition on

13

behalf of all plaintiffs in the MDL.

14

Before we begin, I'd like to

15

know, have you ever been deposed before?

16

A. No.

17

Q. Did you meet with counsel in

18

preparation for this deposition?

19

A. Yes.

20

Q. On how many occasions?

21

A. Five days.

22

Q. Five separate days?

23

A. Yes.

24

Q. Okay. Were they full days?

1 A. No.

2 Q. Okay. Can you describe each
3 day in terms of how many hours
4 approximately you met with counsel?

5 A. Approximately five to
6 6 hours for the first three to four days
7 was -- we spent collecting documentation
8 that the lawyers had requested.

9 Q. Okay. And did all of your
10 meetings concerning collecting
11 documentation or did you also go over,
12 you know, without getting into the
13 substance of any specifics, did you also
14 go over the content of this deposition?

15 A. We did spend time reviewing
16 some of the documentation that was
17 retrieved.

18 Q. Okay. When was the first
19 time that you met with counsel to prepare
20 for this deposition?

21 A. Right after the start of the
22 new year.

23 MR. BARKER: Slow down. Let
24 him finish his question --

1 THE WITNESS: Yes.

2 MR. BARKER: -- before you
3 start answering.

4 THE WITNESS: Yeah.

5 MR. BARKER: And give me an
6 opportunity to object. I don't
7 have a problem with that question,
8 but I may -- if you could wait.

9 THE WITNESS: Right.

10 MR. JANUSH: Sure.

11 BY MR. JANUSH:

12 Q. So after the start of the
13 new year is the first time that you met
14 with counsel?

15 A. Yes.

16 Q. When was the second time?
17 Oh, and when you first met was that one
18 day or sequential days?

19 A. We met for two sequential
20 days after the new year.

21 Q. When did you meet next with
22 counsel?

23 A. The following week for two
24 sequential days.

1 Q. Okay. And following that,
2 did you meet again?

3 A. Yesterday.

4 Q. Yesterday. Okay. Aside
5 from meeting with counsel, did you meet
6 with anyone else to prepare for this
7 deposition?

8 A. No.

9 Q. Did you review any of the
10 transcripts in this litigation in
11 preparation -- preparation for your
12 deposition?

13 A. No.

14 Q. Did you speak with anybody
15 who has been deposed that is a current or
16 former employee of Janssen or Johnson &
17 Johnson or JOM in preparation for this
18 deposition?

19 A. No.

20 Q. Did you speak with any
21 employee who has been deposed in this
22 litigation at all concerning their
23 depositions?

24 A. No.

1 Q. Do you have an understanding
2 as you sit here today why your deposition
3 has been requested?

4 A. Yes.

5 Q. And what is that
6 understanding?

7 A. My understanding is I am
8 here to speak on behalf of Janssen on our
9 suspicious order monitoring program.

10 Q. What is your current job
11 title?

12 A. My current job title is
13 director of controlled substance
14 compliance.

15 Q. And who is your current
16 employer?

17 A. Johnson & Johnson.

18 Q. And I'm going to have you go
19 through briefly your general employment
20 history from, starting with graduating
21 from college, I believe your first job
22 out of college was with Noramco; is that
23 right?

24 A. Yes.

1 Q. Okay. I'd like you to start
2 by discussing that job, that first
3 employment experience with Noramco, and
4 giving us a sense of who Noramco was or
5 is, what they do, and what you did for
6 Noramco. And then we'll transition to
7 your next position. Okay?

8 A. Yes.

9 Q. So let's start with your
10 first job out of the college at Noramco.
11 What was that job and who is Noramco?

12 A. I started with Noramco in
13 the summer of 1986 as a process engineer.
14 Noramco is -- was a wholly owned
15 subsidiary of Johnson & Johnson. We
16 produced active pharmaceutical
17 ingredients for, at the time it was
18 Ortho-McNeil Janssen. So we did -- the
19 client that I supported produced active
20 pharmaceutical intermediates for the
21 product called Tolmetin, which was for
22 tennis elbow.

23 So I was the engineer that
24 was responsible for monitoring the

1 process. I did do configuration of the
2 distributive control system to produce
3 the active ingredients, monitored,
4 dealed -- you know, reported out on
5 production activity. And did project
6 management in regards to equipment,
7 modifications, writing batch logs,
8 writing SOPs and training operators.

9 Q. And for approximately how
10 long did you perform this role as a
11 process engineer for Noramco?

12 A. I spent several years in
13 that engineering track. So then I was
14 promoted to senior process engineer. I
15 got more responsibility for more
16 intermediates. Then I also had an
17 opportunity to do some product transfers
18 from our Belgium location. We did some
19 other active pharmaceutical anti-fungals.

20 So I was involved in getting
21 the plant equipment prepared and doing
22 all the qualification for new equipment
23 for the intermediates that we transferred
24 from Belgium to the United States, the

1 location in Delaware.

2 Q. What are intermediates?

3 A. They're the chemical
4 molecules that are involved -- they are
5 isolated to develop the active
6 pharmaceutical.

7 So it's not the actual
8 active pharmaceuticals, but we made a
9 compound that goes into an antifungal.

10 Q. Okay. And how -- what were
11 the years that you served as a process
12 engineer and a senior process engineer as
13 you've just described?

14 A. Since '86 until '95. Like I
15 said, through the years, I believe in '95
16 at that point I had responsibility for
17 the entire site from process engineering
18 standpoint. And I was introduced to the
19 other production facility at Noramco
20 where they produced codeine and
21 narcotics.

22 So at that point in 1995, I
23 was supporting all the manufacture of the
24 anti-fungals, as well as the narcotics.

1 Q. Let's talk about that role.
2 What was your title in 1995?

3 A. Senior process engineer.

4 Q. Okay. And when you say that
5 you were supporting all of the
6 manufacture of anti-fungals, as well as
7 the narcotic, what does that mean?

8 A. Basically it involved
9 writing SOPs, writing batch logs,
10 training operators, monitoring yield,
11 which is actually the output of all the
12 batches to make sure that there aren't
13 any yield issues or the synthesis --
14 chemical synthesis is running as
15 intended. So just monitoring all the
16 chemical reactions and production
17 activities.

18 Q. What role did you play, if
19 we can break it down with respect to
20 monitoring narcotic production?

21 A. Well, at the time as an
22 engineer I made sure the batch logs were
23 written to produce the -- the compounds
24 which was codeine and morphine at the

1 time. Make sure that it was isolating
2 the morphine and codeine, and that we
3 were doing the steps necessary to purify
4 it to its active pharmaceutical
5 ingredient state.

6 Q. And at that time, this is
7 '95 through what we're speaking about?

8 A. It was basically '93 to '95,
9 I had -- that's when the narcotics were
10 introduced from my bandwidth.

11 Q. Okay. So your first
12 experience dealing with narcotics started
13 in 1993, and from 1993 through 1995, you
14 were involved in addressing batch logs,
15 and taking steps necessary to ensure that
16 the purity of the drug was -- was correct
17 in its -- in the sense of the active
18 pharmaceutical ingredient was what,
19 correctly being manufactured?

20 I'm trying to understand
21 exactly in layman's terms.

22 A. Right. Right.

23 Q. We're going to break this
24 down. I don't know what a batch log is.

1 I'm going to have you explain that too.

2 A. Sure. So Noramco was under
3 FDA regulations for good manufacturing
4 practices. And as part of those
5 guidelines, you needed to produce your
6 active ingredients the same way
7 consistently to meet specifications.

8 So every active
9 pharmaceutical had a specification that
10 said this is the level and purities that
11 were permitted to be present in the level
12 at which it's allowed to be present.

13 So as the production
14 engineer supporting the actual batch
15 records, which is the step-by-step
16 process that the operator follows to
17 produce the active ingredient, I made
18 sure that they followed the batch logs,
19 that we isolated the product, that it
20 tested and met the specifications.

21 Q. Okay. And at that time, '93
22 to '95, you were just addressing codeine
23 and morphine as it concerned narcotics;
24 is that right?

1 A. Yes.

2 Q. And when you were addressing
3 codeine and morphine, were you -- was
4 Noramco producing codeine and morphine
5 only for Noramco or was Noramco producing
6 codeine and morphine for external
7 customers as well?

8 MR. BARKER: Object to form.

9 BY MR. JANUSH:

10 Q. Do you know what I mean by
11 external customers?

12 A. Yes.

13 Q. What -- how would you
14 describe an external customer?

15 A. Outside of J&J.

16 Q. Okay. So I just want to
17 make sure we're on the same page since
18 there was an objection.

19 Was Noramco manufacturing
20 codeine and morphine for customers
21 outside of J&J?

22 MR. BARKER: Object to form.

23 BY MR. JANUSH:

24 Q. In this 1993 to 1995 time

1 period?

2 MR. BARKER: Object to form.

3 MR. JANUSH: You've objected
4 twice.

5 MR. BARKER: You added a
6 time frame that addressed part of
7 my objection. So you now have a
8 different question.

9 MR. JANUSH: Okay.

10 MR. BARKER: So I'm
11 objecting to the different
12 question.

13 MR. JANUSH: Fair enough.

14 BY MR. JANUSH:

15 Q. You can answer.

16 A. I don't recall who the
17 customers were, but I believe there were
18 some codeine and morphine customers that
19 were not J&J.

20 Q. Okay. Take us forward from
21 1995. What happened next?

22 A. In 1995 I was asked to lead
23 a technology transfer team where J&J had
24 made the decision to shut down an active

1 pharmaceutical ingredient manufacturing
2 location in Puerto Rico and relocate the
3 processes to the Noramco site in Athens,
4 Georgia. So for two years I was part of
5 this team to collect all of the related
6 equipment information, analytical
7 information, batch records, and chemistry
8 documentation for these active
9 pharmaceutical ingredients, they were
10 non-narcotic, that Janssen produced.

11 Q. Okay. And this lasted from
12 1995 to 1997; is that right?

13 A. Yes.

14 Q. What happened in 1997?

15 A. In 1997 I was asked to be
16 the intermediate plant manager for the
17 original plant that I started as a
18 process engineer. So I was managing the
19 operators and the supervisors in the
20 production of the antifungal, seven-day
21 operation.

22 Q. And where was this original
23 plant?

24 A. In Wilmington, Delaware, at

1 the Noramco location.

2 Q. And what did you do in that
3 role?

4 A. I had the overall
5 supervision of the operators and the
6 supervisors. I ensured that we produced
7 our product meeting the regulatory
8 requirements from the FDA standpoint, as
9 well as EPA and the other regulatory
10 agencies that are involved with the
11 production of this antifungal,
12 nonnarcotic.

13 Q. And what was the name of
14 this antifungal nonnarcotic?

15 A. The -- the intermediate we
16 called TA-24 which went into imazalil.

17 Q. How do I spell that?

18 A. I-M-A-Z-I-L-I-L. Or
19 A-L-I-L.

20 Q. And how long did you stay in
21 that role that you started in 1997 as the
22 interim plant manager for the Wilmington,
23 Delaware, site?

24 A. Until 2001.

1 Q. What happened in 2001 with
2 your employment?

3 A. I moved over to a process
4 engineering role.

5 Q. And what was that role?

6 A. It was validation manager.
7 So I was -- I had engineers reporting to
8 me, and our role was to produce all of
9 the FDA required documentation
10 surrounding validation of our processes.
11 So if we make any changes in our chemical
12 synthesis or the isolation or the
13 particle sizing, we are required by FDA
14 guideline, good manufacturing practices,
15 to have a validation document that
16 demonstrates that for three or four
17 batches, we can consistently produce this
18 active pharmaceutical to meet the
19 specifications outlined in the document.

20 Q. And that role lasted from
21 2001 to what year?

22 A. Till 2005.

23 Q. And as a validation manager,
24 did you also oversee the validation of

1 the raw ingredients of narcotics?

2 A. I did cover the validation
3 of the narcotic process, the APIs.

4 Q. And what does API stand for?

5 A. Active pharmaceutical
6 ingredients.

7 Q. Okay. Which narcotics did
8 you cover overseeing the validation of
9 between 2001 and 2005?

10 A. Codeine, morphine,
11 Oxycodone, hydrocodone, and then the
12 intermediate steps had to be validated as
13 well. So you had the -- the crude
14 Oxycodone and purified steps as well as
15 the various steps involved with
16 hydrocodone. And I mentioned codeine,
17 morphine.

18 Q. And how did your employment
19 change, if at all, in 2005?

20 A. I was asked to lead a
21 project, an IT project from the business
22 standpoint. At the time Noramco was
23 asked -- we were onboarding our -- onto
24 the Janssen Supply Chain, SAPERP system.

1 It's an enterprise -- basically inventory
2 control, IT platform, where you are
3 tracking the -- what goes into the batch,
4 and what is isolated into the batch, and
5 end to end, from receipt of raw material
6 to shipments. So it's an IT system that
7 used to track all the movements, and I
8 was asked to lead the project. So that's
9 what I did from 2005 until I went live in
10 January 2006. And then I was asked to
11 do -- to lead -- in IT, I was in IT at
12 the time, to lead a group that would
13 sustain the IT system and make sure that
14 it was operating as it was intended.

15 Q. And that was in 2006?

16 A. Yes.

17 Q. What happened after 2006,
18 how did your employment capacity change?

19 A. In 2006 we -- we did a few
20 more other SAP projects, barcoding, and
21 more updates to the SAP processes. And
22 then in 2007, I was asked to expand my
23 bandwidth and take over DEA compliance
24 and security.

1 Q. And what does it mean to
2 take over DEA compliance and security for
3 Noramco?

4 A. Well, I left IT to get a
5 role in supply chain. And at the time,
6 supply chain, the leader had DEA and
7 compliance -- DEA and security under him.
8 And his bandwidth was stretched and he
9 didn't have the time to spend with the
10 group and he asked me to step in and
11 provide guidance and manage the group of
12 employees that were supporting the DEA
13 compliance and security processes at both
14 locations, Athens and Wilmington,
15 Delaware.

16 Q. And -- and what kind of
17 day-to-day responsibilities would you
18 have supporting DEA compliance and
19 security?

20 A. Well, the -- the group, the
21 manager, and the specialist, they did the
22 transactional work. So my work involved
23 more of the high level processing, making
24 sure that we are inspection ready, that

1 we have the same processes and SOPs
2 across both sites when it's dealing with
3 a DEA inspection. Make sure we have
4 similar security procedures. That we're
5 providing effective controls to prevent
6 diversion.

7 And also my role was
8 engaging DEA when necessary involving
9 policy interpretations or other
10 discussions related to DEA items.

11 Q. And when you speak about
12 SOPs, you're referring to standard
13 operating procedures; is that right?

14 A. Yes.

15 Q. So throughout this
16 deposition, every time you use the term
17 "SOP," we'll agree that that means
18 standard operating procedures?

19 A. Yes.

20 Q. Okay. With respect to this
21 role, this DEA compliance and security
22 role within the supply chain at Noramco,
23 you started in 2007. When did that role
24 end?

1 A. I no longer had oversight of
2 DEA compliance and security with the
3 divestiture of Noramco in 2016.

4 Q. Okay. So did there come a
5 time between 2007, when you oversaw
6 Noramco's supply chain, and 2016, when
7 Noramco was divested, that you
8 simultaneously had another role within
9 Johnson & Johnson?

10 A. Yes.

11 Q. And can you describe that?

12 A. In 2011, I was asked to lead
13 a project to introduce quota
14 understanding with -- outside of Noramco
15 into Janssen Supply Chain for -- so I was
16 involved in this project where I updated
17 existing SOPs outside of Noramco. I
18 became aware and visited the other
19 locations that did the manufacturing of
20 the Janssen products.

21 And over -- from 2011 until
22 2012, 2012 March was when I was formally
23 given direct -- I had people at the sites
24 reporting into me. So I had the

1 distribution centers and the
2 manufacturing formulating locations
3 reporting in through me as of March of
4 2012.

5 And we had developed this
6 organization called controlled substance
7 compliance for Janssen Supply Chain.

8 Q. Is it fair to say in
9 March 2012, you took on a secondary or
10 additional role called director of
11 controlled substance compliance for
12 Janssen?

13 A. Yes.

14 Q. And when you took on that
15 role as director of controlled substance
16 compliance for Janssen, you remained in
17 the prior role as the head of DEA
18 compliance and security within the supply
19 chain for Noramco?

20 A. Yes.

21 Q. Is that right?

22 A. Yes.

23 Q. Sounds like a lot of work.

24 A. Yes.

1 Q. Let's go back to Noramco for
2 a moment. At all times that you were
3 overseeing the DEA compliance and
4 security and quota issues concerning
5 Noramco, was Noramco only making the raw
6 narcotic ingredients or did Noramco also
7 manufacture the end product, the actual
8 pill, as an example?

9 A. We did not make final
10 product pill. Noramco took the narcotic
11 raw materials and produced active
12 pharmaceutical ingredient powders.

13 Q. Okay. So is it a correct
14 statement that Noramco would get orders
15 from outside companies, as well as
16 internally from -- as an example, a
17 Johnson & Johnson family company, such as
18 Janssen, to provide the raw powder that
19 would be a Schedule II underlying
20 substance for inclusion into a narcotic
21 pill?

22 A. Noramco did provide active
23 pharmaceutical ingredient powder to
24 Janssen locations as well as outside of

1 Janssen.

2 Q. Okay. Before we move on
3 from employment history, I just want to
4 make sure that I have this -- this down.

5 You addressed that in March
6 of 2012, you took on the additional role
7 of being director of controlled
8 substances compliance -- substance
9 compliance; is that right?

10 A. Yes.

11 Q. And that was for Johnson &
12 Johnson?

13 A. That was for the Janssen
14 Supply Chain.

15 Q. Okay. And when we speak
16 about the Janssen Supply Chain, I know of
17 another company called JOM. Do you know
18 who JOM is?

19 A. Janssen Ortho-McNeil is the
20 legal entity name of the distribution
21 centers in which -- under J&J.

22 Q. Okay. So when I see or when
23 we see JOM as an emblem or insignia on
24 letterhead, that's referring to Janssen

1 Ortho-McNeil; is that right?

2 A. Yes.

3 Q. Okay. And Janssen

4 Ortho-McNeil, or JOM, oversaw supply

5 chain distribution for Janssen's

6 pharmaceutical products; is that right?

7 MR. BARKER: Objection.

8 THE WITNESS: Yes.

9 BY MR. JANUSH:

10 Q. JOM, for short, oversaw the

11 shipments of products from Janssen to

12 wholesaler customers, as an example; is

13 that correct?

14 A. JOM received orders for

15 wholesalers and shipped orders that were

16 approved to the wholesalers that went

17 through.

18 Q. Okay. And your function as

19 director of controlled substance

20 compliance operated out of JOM or out of

21 Janssen or Johnson & Johnson? Which is

22 it?

23 A. My role was in Janssen

24 Supply Chain, which I was located in

1 Wilmington, Delaware under Noramco.

2 Q. So you were simultaneously
3 working for Noramco addressing DEA
4 compliance issues, quota issues, security
5 issues for Noramco, right?

6 A. Yes.

7 Q. And at the same time you
8 were based out of Noramco's site in
9 Wilmington, Delaware. And you were
10 overseeing Janssen's compliance with
11 controlled substances; is that right?

12 A. Noramco was part of Janssen
13 Supply Chain. They were the active
14 pharmaceutical ingredient supplier. So I
15 expanded my support from just the active
16 pharmaceutical ingredient manufacture
17 through formulation to distribution.

18 Q. But to be clear, Noramco was
19 a wholly separate company than Janssen,
20 right?

21 A. It was a wholly owned
22 subsidiary of Johnson & Johnson.

23 Q. Right. And Noramco made the
24 raw ingredient that went into Janssen's

1 narcotic drugs as well as other non-J&J
2 customers' narcotics, right?

3 A. Noramco provided API for
4 Janssen as well as other customers.

5 Q. That's a long way of saying
6 right to my other question -- to my
7 question, correct?

8 A. But Noramco -- the
9 leadership reported in to Janssen Supply
10 Chain.

11 Q. All right. Why don't you
12 explain that.

13 A. The employees that worked at
14 the Wilmington and Athens facilities, the
15 operations personnel, reported in to
16 Janssen Supply Chain.

17 Q. Okay.

18 A. Under the organization
19 structure, even though it was a legal
20 entity subsidiary.

21 Q. So Janssen -- Janssen
22 oversaw Noramco?

23 MR. BARKER: Objection. Let
24 her finish her answer. She wasn't

1 quite done before you started the
2 next question.

3 MR. JANUSH: My apologies.
4 I thought she was finished.

5 BY MR. JANUSH:

6 Q. What else do you have to
7 add? I apologize.

8 A. So Noramco had its own legal
9 entity; however, the operations
10 manufacturing personnel reported in
11 through Janssen Supply Chain.

12 Q. And so my question was -- so
13 Janssen Supply Chain oversaw Noramco; is
14 that right?

15 A. The organization reporting
16 went into Janssen Supply Chain.

17 Q. And what does that mean, the
18 organization reporting went into Janssen
19 Supply Chain?

20 A. From the performance
21 management, our goals and objectives,
22 they had to be reported up into Janssen
23 Supply Chain.

24 Q. Janssen Supply Chain

1 supervised Noramco?

2 A. The operations
3 manufacturing; however, the marketing and
4 sales was not part of Janssen Supply
5 Chain. That was a separate entity called
6 Worldwide Narcotic Franchise.

7 Q. So Noramco had a separate
8 sales and marketing division called
9 Worldwide Narcotic --

10 A. It was the narcotic -- the
11 narcotic --

12 Q. Let me finish.

13 MR. BARKER: You need to let
14 him finish as well.

15 BY MR. JANUSH:

16 Q. Yeah, because it -- and
17 we'll do our best. I know we're not
18 doing this purposefully.

19 So let me ask my question
20 again.

21 Noramco had a separate sales
22 and marketing division called Worldwide
23 Narcotic unit?

24 A. The Narcotic Franchise.

1 Q. Franchise. And during your
2 time with Noramco, who oversaw the sales
3 and marketing of the Worldwide Narcotic
4 Franchise?

5 A. Matthew Martin.

6 Q. Was he with Noramco in 2016
7 when Noramco was divested?

8 A. Yes.

9 Q. Is -- that's a yes?

10 A. Yes, he was with Noramco.

11 Q. Do you know if he moved over
12 to the new co, the new Noramco company --

13 A. Yes.

14 Q. -- when Noramco was
15 acquired?

16 A. Yes.

17 Q. Do you know if he's still
18 there today?

19 A. No, I don't.

20 Q. Okay. Have you stayed in
21 touch with folks who you worked with at
22 Noramco who may have moved over to the
23 new company after divestiture?

24 A. A few.

1 Q. And who would those folks
2 be?

3 A. They would be the DEA
4 compliance personnel that at one time
5 reported to me.

6 Q. And who's that?

7 A. Gene Haines and Ann
8 Strusowski. She had a previous role in
9 DEA compliance at Noramco.

10 Q. Okay. Following the
11 divestiture of Noramco by Johnson &
12 Johnson in 2016 and through the present
13 date, has your role remained the same as
14 director of controlled substances
15 compliance?

16 A. I remained in a role of
17 controlled substance compliance. I've
18 just expanded outside the U.S. in my
19 support.

20 Q. Can you explain how your
21 role has changed from 2016 to the present
22 date?

23 A. From 2016 to 2017, I -- I
24 continued to support the manufacturing

1 locations within Janssen Supply Chain.

2 And then in January 2018 I moved to a
3 regulatory compliance role in this global
4 organization, J&J regulatory compliance,
5 where I now have a regulatory compliance
6 role for all of the -- global, from
7 manufacture to distribution.

8 Q. And does this include opiate
9 products?

10 A. It includes all controlled
11 substances that J&J handles.

12 Q. And did you retain the title
13 of director of controlled substances
14 compliance -- controlled substance
15 compliance in January of 2017 or did you
16 take on a new title?

17 A. The title remained the same,
18 director of controlled substance
19 compliance.

20 Q. So the title remained the
21 same, but your oversight, the scope of
22 your role, grew; is that right?

23 A. Yes.

24 (Document marked for

1 identification as Exhibit

2 Dempsey-1.)

3 BY MR. JANUSH:

4 Q. I'm going to mark a document
5 as Exhibit 1, which is a year-end
6 performance review from 2017, and the
7 Bates number for this document is
8 JAN-MS-03120846.

9 And I really want to -- I
10 want to note that this is for January 1,
11 2017, through December 31, 2017; is that
12 right?

13 That's up in the upper
14 right-hand corner. Do you see that?

15 A. Yes, yes.

16 Q. Okay. All right. And --
17 and in the middle of the page, I'm going
18 to underline to draw your attention to it
19 on the screen so you can follow me. It
20 says, "She does this very well," and the
21 this is that, referring to -- I'll let
22 you go -- actually read up a little bit.

23 "Michele is such a strong
24 asset in her area and is making important

1 impact to our products and company.
2 Related to the how, Michele is very
3 strong connected to the key players
4 within and outside the company in
5 relation to controlled substances. She
6 does this very well. Knows how to make
7 and sustain these connections, being with
8 DEA, regulatory bodies or internal
9 stakeholders within the different
10 segments and make the necessary impact.
11 2017 and 2018 will be a transition year
12 for Michele.

13 "One way in delivering the
14 CSC/COE processes and organization and
15 otherwise, and Michele transitioning from
16 being more tactical in executing things
17 towards becoming more global, setting
18 direction and expectations and enabling
19 the CSC activities to be done. Still an
20 area where I see Michele somewhat
21 struggling."

22 Did I read correctly through
23 that point?

24 A. Yes.

1 Q. What -- what was your
2 supervisor Gianluca Vissani -- or
3 actually, this was an evaluation done by
4 Stefan Bouckaert -- is that right?

5 A. Stefan Bouckaert.

6 Q. Bouckaert. What -- what was
7 Stefan Bouckaert addressing that an area
8 where -- where you were viewed to be
9 somewhat struggling?

10 MR. BARKER: Object to form.

11 THE WITNESS: Is there a
12 question?

13 BY MR. JANUSH:

14 Q. I think you can read it on
15 the screen. If not, I can read it for
16 you.

17 A. The --

18 Q. My question was, what was
19 Stefan Bouckaert addressing concerning an
20 area where -- is it a he or a she,
21 Stefan?

22 A. He.

23 Q. Where he sees Michele
24 somewhat struggling.

1 MR. BARKER: Object to form.

2 BY MR. JANUSH:

3 Q. You can answer.

4 A. The -- the challenge was, in
5 his mind, I should not be involved in
6 local activities like writing quota
7 letters or supporting DEA inspections.
8 He really wanted to see me at a global
9 level setting direction and ensuring that
10 the local quality ownership is done and
11 that they are comfortable in executing
12 inspections and engaging DEA on the
13 quota-related questions and the policy
14 questions. He wanted more of a global
15 strategic. And -- and it was -- the
16 reason he said it's a transition year is
17 we were building that inhouse knowledge
18 at a local level.

19 Q. I want to take you back to
20 slightly before 2017 when your role was
21 less global in nature. Can you describe
22 what the role of director of controlled
23 substance compliance is and what you were
24 entrusted to do?

1 A. Well, in 2000 -- if --

2 Q. I'm taking you back before
3 this year-end review.

4 A. Before this year-end report,
5 my job description involved ensuring that
6 end-to-end supply chain, all locations
7 were compliant with the local
8 regulations.

9 So, at this time in 2016, I
10 had to ensure that all of the
11 manufacturing locations, not just the
12 U.S. ones, were compliant, which
13 involved -- I did do on-site audits and
14 working with the local team, making sure
15 everything was documented in SOPs and
16 that we understood what the regulatory
17 authority of the competent national
18 authority for the country expected of the
19 local site.

20 So his comment here was that
21 I needed to focus more on outside the
22 U.S. in this more global role.

23 Q. And I'm taking you back
24 before 2017. Did you have a role in

1 overseeing suspicious order monitoring
2 for Janssen or Johnson & Johnson?

3 A. It went back to Noramco.
4 Because Noramco was obligated to have a
5 suspicious order monitoring program. And
6 then when, in 2012 I had the two
7 distribution centers reporting into me.
8 I had input on their order monitoring
9 system as well.

10 Q. I'm separating out Noramco
11 in -- well, and Janssen. Okay.

12 So let's start with Noramco.
13 Your -- your role in overseeing
14 suspicious order monitoring for Noramco
15 was what?

16 MR. BARKER: Object to form.
17 BY MR. JANUSH:

18 Q. Can you describe your role
19 overseeing suspicious order monitoring
20 for Noramco?

21 A. As I mentioned before, my
22 role as the director of DEA compliance
23 and security is I ensured that the
24 manager and the specialist, that we had

1 SOPs in place that would describe our
2 process for monitoring all the orders
3 that we received from the customers.

4 And from an active
5 pharmaceutical ingredient standpoint,
6 everything is very controlled because DEA
7 grants us quota and we only produce to
8 the quota that DEA has provided us. And
9 in order -- our order monitoring program
10 for those customers, they have to --
11 besides the 222 and have a valid DEA
12 license, they had to provide a
13 certificate of a procurement quota, which
14 was a document that confirmed that they
15 have quota from DEA to receive our
16 product.

17 So at high level, that was
18 what was required from that standpoint.
19 We did supply active pharmaceutical
20 ingredients to researchers and we had
21 stricter rules for those including
22 quantity, protocols from them, local DEA
23 approval for our product. So we did have
24 an order monitoring process in place.

1 Q. And then moving over to the
2 manufacturing side for Janssen, the role
3 of overseeing suspicious order monitoring
4 can be defined as what by you?

5 MR. BARKER: Object to form.

6 THE WITNESS: Anyone that
7 holds a license with DEA that
8 involves distribution you're
9 required to operate a system to
10 monitor orders for size, frequency
11 and patterns.

12 BY MR. JANUSH:

13 Q. And you oversaw suspicious
14 order monitoring on behalf of Johnson &
15 Johnson's Schedule II and other scheduled
16 products; is that right?

17 MR. BARKER: Object to form.

18 THE WITNESS: I had
19 responsibility and oversight in
20 2012 for the personnel at JOM that
21 was involved with reviewing orders
22 for release.

23 BY MR. JANUSH:

24 Q. You were the director of the

1 unit that oversaw controlled substance
2 compliance from 2012 through, in fact,
3 the present date; is that right?

4 A. Through December 31, 2017.

5 Q. Okay. And what happened on
6 December 31, 2017?

7 A. Local quality accepted
8 ownership of controlled substance
9 compliance, and I moved to the global
10 oversight role within J&J regulatory
11 compliance.

12 Q. You were still, however,
13 involved in suspicious order monitoring,
14 standard operating procedures and design
15 after December -- December of 2017; isn't
16 that right?

17 A. Yes.

18 Q. You were not just involved,
19 you were a point person involved in
20 overseeing the redesign of suspicious
21 order monitoring for Janssen and Johnson
22 & Johnson after December of 2017; isn't
23 that also right?

24 A. As of January 2018, my role

1 is more of an oversight, provide guidance
2 on interpretation, and ensure that the --
3 the local quality are implementing the
4 controls per the regulations.

5 Q. You're not taking the
6 position that you weren't involved in
7 designing a revised suspicious order
8 monitoring system as of January 1, 2018,
9 for Johnson & Johnson, are you?

10 MR. BARKER: Object to form.

11 THE WITNESS: No, I provide
12 input into the system from an
13 oversight perspective.

14 BY MR. JANUSH:

15 Q. You were the leader; isn't
16 that right?

17 A. In 2018 I was not the
18 leader. Our local quality at that site,
19 DEA compliance reports into local
20 quality. They had the accountability for
21 the program.

22 Q. And you were very much
23 involved in the redesign of the
24 suspicious order monitoring program in

1 2018, weren't you?

2 MR. BARKER: Object to form.

3 THE WITNESS: The redesign?

4 I don't -- no, I don't understand
5 what you mean by redesign.

6 BY MR. JANUSH:

7 Q. Modifications. Do you
8 understand what modifications to a system
9 means?

10 A. Yes, I understand what
11 modification to a system means. But I'm
12 looking at 2018 and I know that there is
13 a project to enhance our program. And I
14 was providing input into that project.

15 Q. Okay. And -- and by
16 enhance, you mean modify the suspicious
17 order monitoring program, don't you?

18 A. No. I mean enhance it. We
19 had learned that there may be other
20 information that DEA has required, and we
21 wanted to make sure that our program is
22 delivering what DEA expects. And so we
23 are making those enhancements so we're
24 more robust and ready for a DEA

1 inspection should the new requirements be
2 reviewed. But at this time, our program
3 has been reviewed with DEA.

4 Q. When you say, "At this time,
5 our program has been reviewed with DEA,
6 when was the last review of your program
7 with DEA?

8 A. The -- every time they come
9 in and inspect the distribution centers,
10 they ask for our suspicious order
11 monitoring procedures. So the last time
12 they got our procedures were in
13 December 2017.

14 Q. And that was in conjunction
15 with an inspection of what site?

16 A. Kentucky distribution site.

17 Q. Now, I'm going to turn your
18 attention to the page that ends in Bates
19 stamp 50 on Exhibit 1. And this goes
20 hand in hand with something that you were
21 just testifying about. You were talking
22 about the -- let's see -- that you
23 learned that there may be other
24 information that the DEA has required.

1 So first I want to know,
2 what's that other information that the
3 DEA required that you were speaking to in
4 more recent years like 2017?

5 A. Well, we were constantly
6 engaging DEA to understand if they -- if
7 there's new expectations. And in 2017 --
8 we were on the e-mail list from the DEA
9 website. There was an e-mail that we
10 received from DEA in regards to
11 Mallinckrodt, a settlement with
12 Mallinckrodt.

13 And in that e-mail we heard
14 DEA say that there may be a requirement
15 for more downstream analysis by the
16 manufacturer.

17 Q. Okay. So let's go to this
18 second bullet that I'm drawing a line
19 through that reads, "The U.S. environment
20 changing because of the opioid epidemic
21 increased the workload for JOM."

22 Can you explain what this
23 sentence meant? This is what you wrote
24 as part of your comment in your personnel

1 review; is that right?

2 A. It was my self-assessment.

3 Q. Okay. What -- what did that
4 statement mean?

5 A. That enhancements will be
6 needed beyond what we currently are
7 doing. And that because there's more
8 requirements to perform on order reviews,
9 that this could impact Janssen
10 Ortho-McNeil in how they do the order
11 monitoring process, as well as our due
12 diligence and our compliance meetings,
13 right.

14 So, I'm trying to remember
15 that -- that we are also preparing for a
16 launch of a new product, which --

17 Q. Let's --

18 A. -- which -- I mean, that
19 was -- so that was why the increased
20 workload for JOM. Because of these
21 new -- because of the Mallinckrodt
22 expectations to know downstream, that
23 there is more data that we'll have to
24 review, so there's more workload on the

1 specialists that do the day-to-day order
2 monitoring.

3 Q. Okay. And when you speak
4 about the Mallinckrodt DEA action, are
5 you referring to the 2017 DEA action that
6 determined Mallinckrodt had an obligation
7 to know customers' customer? In other
8 words, to know where its sales were going
9 to the end pharmacy?

10 A. I believe that the e-mail
11 that I received from DEA said that they
12 had -- they had data downstream of where
13 the wholesalers were shipping --

14 Q. Right.

15 A. -- that needed -- that could
16 have told them about the diversion of
17 their products.

18 Q. And that's --

19 A. The difference between data
20 that was being analyzed.

21 Q. And so we're talking about
22 the same thing. We're not cross-talking.
23 When I say knowing your customers'
24 customer, you understand that to knowing

1 if you're a seller like Mallinckrodt, and
2 you are selling to a wholesaler, and that
3 wholesaler is selling to a drug store,
4 for example a CVS or a Walgreens, that's
5 an example, and if Mallinckrodt had data
6 as to where customers' customer was
7 stocking its product, it should have
8 known that. Do you understand? We're on
9 the same page on that, aren't we?

10 MR. BARKER: Object to form.

11 THE WITNESS: I believe the
12 way DEA commented is you know the
13 customer and the downstream data,
14 where it goes. I don't believe
15 they say know your customers'
16 customer. But that was the intent
17 that, if you had this data
18 downstream that indicated where
19 your products go, you should have
20 been looking at it.

21 BY MR. JANUSH:

22 Q. And 2017 wasn't the first
23 time that you had been introduced to the
24 concept of knowing who your customers'

1 customer is; is that right?

2 A. That was the first time that
3 I became aware of the downstream data
4 that should be used. At the point up
5 till then, it was know my customer, which
6 were the wholesalers.

7 Q. And when you say that was
8 the first time that you had been -- that
9 you became aware of the downstream data
10 that should be used, what does that mean?

11 A. That prior to that I never
12 heard DEA tell the manufacturer that you
13 needed to know beyond your customer, that
14 information.

15 Q. Did you hear of other
16 manufacturers engaging in best practices
17 to know your customers' customer, to know
18 that downstream information as a
19 manufacturer of opioid products?

20 MR. BARKER: Object to form.

21 THE WITNESS: I had not
22 heard of many manufacturers that
23 were using that downstream data
24 beyond the wholesaler up until DEA

1 sent that e-mail.

2 I had been to some
3 conferences where there was some
4 talk on chargebacks, but with
5 brand products, there was
6 challenges.

7 BY MR. JANUSH:

8 Q. So my question wasn't
9 whether you had been aware of many
10 manufacturers who were, as part of their
11 best practices, using data to know their
12 customers' customers, my question was,
13 did you know of other manufacturers who
14 were in fact doing that and investigating
15 their customers' customers with
16 chargeback data and other data before
17 2017?

18 MR. BARKER: Object to form.

19 THE WITNESS: I do not
20 recall discussing the use of
21 chargeback data with any other
22 manufacturer. I was not aware.

23 (Document marked for
24 identification as Exhibit

1 Dempsey-2.)

2 BY MR. JANUSH:

3 Q. I'm going to mark as
4 Exhibit 2 a document called a regulatory
5 agency contact report. I believe it's
6 dated 2011. And it concerns an
7 October 21, 2011, or October 20, 2011,
8 meeting with DEA.

9 And the summary on the front
10 page says, "Noramco participated in a
11 meeting with DEA in Washington to discuss
12 future volumes and impact on aggregate
13 production quota."

14 Do you see that?

15 And the Bates number is
16 JAN-00060000953.

17 But do you see the summary
18 that I was drawing your attention to on
19 the first page?

20 A. Yes.

21 Q. Okay. Do you remember
22 seeing this document?

23 A. I remember that I wrote it.

24 Q. That was going to be my next

1 question. I thought so. So these are
2 notes of your minutes with the DEA on
3 Noramco -- joint Noramco and Janssen
4 letterhead; is that right?

5 A. Yes.

6 Q. Okay. And there's a lot
7 here to cover, so I'm going to try and
8 just cover five or so different topic
9 areas and go through this document as
10 quickly as I can.

11 The first issue I'd like to
12 cover is on the second page of the
13 document, ending in Bates number 54.

14 And it says "Meeting
15 purpose: Present 2012 and beyond Noramco
16 volumes that impact aggregate production
17 quota."

18 Do you see that?

19 A. Yes.

20 Q. And so can you describe
21 exactly what -- what the goal of this
22 meeting was?

23 A. The meeting purpose was for
24 sales and marketing to present their --

1 what they are projecting as the demand
2 for Noramco with DEA.

3 DEA is responsible for
4 setting up the aggregate production
5 quota. And they request that bulk
6 manufacturers provide information to them
7 that they can review as they set up the
8 aggregate production quotas.

9 Q. Okay. And your meeting is
10 with Denise Curry, the deputy director,
11 office of diversion control; is that
12 right?

13 A. Yes.

14 Q. And Dr. Chris Sannerud,
15 section chief for quota and UN reporting
16 unit, Office of Diversion Control. True?

17 A. Dr. Sannerud, yes.

18 Q. Okay. And Stacy
19 Harper-Avilla, the quota chief for quota
20 and UN reporting unit, Office of
21 Diversion and Control.

22 And do you remember who Adam
23 Goldsmith and -- and Greg Kavanaugh are
24 or were in terms of their roles with the

1 DEA?

2 A. Greg Kavanaugh was a -- in
3 the quota group. He was one of the --
4 the specialists that reviewed requests.

5 Q. And how about Adam
6 Goldsmith?

7 A. I don't recall.

8 Q. And you were there with Mike
9 Kindergan, global vice president sales
10 business development for Noramco; is that
11 right?

12 A. Yes.

13 Q. And Bill Grubb who's the --
14 was the senior director U.S. sales and
15 marketing?

16 A. Yes.

17 Q. And those were the only two
18 that joined you at this meeting on your
19 side; is that right?

20 A. Yes.

21 Q. Okay. Now, moving down to
22 your notes. At this meeting you
23 presented a slide deck to the DEA, did
24 you not?

1 A. I personally did not
2 present. Bill Grubb and Mike Kindergan
3 did.

4 Q. Okay. And you wrote the
5 notes concerning the presentation; is
6 that right?

7 A. I was the scribe.

8 Q. Okay. So I want to focus
9 first on Slide 2, oxy market, Noramco
10 message, IR growth in the slide is
11 conservative and could be higher.
12 Noramco supplies bulk of the IR market.

13 Did you convey to the DEA
14 that -- that Noramco supplied the bulk of
15 the Oxycodone market?

16 MR. BARKER: Object to form.
17 BY MR. JANUSH:

18 Q. As of 2011?

19 MR. BARKER: Object to form.

20 THE WITNESS: Bill Grubb and
21 Mike Kindergan presented that
22 information.

23 BY MR. JANUSH:

24 Q. And what does the IR market

1 stand for? That -- that stands for
2 immediate release; is that right?

3 A. IR does stand for immediate
4 release.

5 Q. Okay. And it looks like in
6 the first bullet, Dr. Sannerud was asking
7 why OxyContin volume was decreasing and
8 what was taking its place. And Bill,
9 that's Bill Grubb, right?

10 A. Yes.

11 Q. Responded that in the
12 branded SR space, and what does SR stand
13 for?

14 A. SR stands for suspended
15 release.

16 Q. In the branded suspended
17 release space, also known as ER, extended
18 release, right?

19 MR. BARKER: Object to form.

20 THE WITNESS: I don't recall
21 if it meant exactly extended
22 release.

23 BY MR. JANUSH:

24 Q. Okay. There are now other

1 choices available such as Opana, Exalgo,
2 and Nucynta which are likely being
3 prescribed in place of the OxyContin. He
4 stated that Nucynta in particular has
5 less side effects.

6 I'm going to stop there. Do
7 you know what data led Bill Grubb to --
8 to state to the DEA that Nucynta has less
9 side effects than OxyContin?

10 MR. BARKER: Objection.

11 THE WITNESS: No, I do not.

12 BY MR. JANUSH:

13 Q. And then the next sentence
14 states, "Also, the decline could be due
15 to the abuse deterrent formulation having
16 the intended impact, (with abusers), and
17 mentioned reports that the reformulated
18 OxyContin pill swells in the throat if
19 not swallowed quickly."

20 Did I read that correctly?

21 A. Yes.

22 Q. Do you know what the abuse
23 deterrent formulation was that -- that
24 Bill Grubb was speaking to?

1 MR. BARKER: Object to form.

2 THE WITNESS: I don't

3 recall.

4 BY MR. JANUSH:

5 Q. Concerning -- I'll ask it
6 differently.

7 Do you know whether Bill
8 Grubb was speaking to an abuse deterrent
9 formulation concerning Nucynta at this
10 time?

11 MR. BARKER: Object to form.

12 THE WITNESS: I don't

13 recall.

14 BY MR. JANUSH:

15 Q. Do you know whether Nucynta
16 had an abuse deterrent label approved by
17 the FDA?

18 A. No.

19 Q. No, you don't recall or no,
20 it did not?

21 A. My recollection is no, it
22 did not.

23 Q. Okay. I'm going to jump
24 forward to the page ending in 56. And

1 specifically Slide 15. And I'm marking
2 on the screen where I am if I can help
3 you if you need to look at your monitor.
4 And it's addressing oxymorphone API for
5 sale.

6 Dr. Sannerud asks: Did the
7 FDA act on the Endo citizen petition?

8 Bill said, "Yes. FDA agreed
9 with the purity requirements but not
10 other aspects of the petition."

11 Dr. Sannerud asked if
12 Noramco will be supplying the brand Opana
13 in 2012, and Bill said, "Not
14 commercially, but yes, we have worked
15 with them and are in discussions that
16 could lead to a new qualification volumes
17 in 2012."

18 Do you see that?

19 A. Yes.

20 Q. Did Noramco work with Endo
21 in supplying oxymorphone for Opana?

22 MR. BARKER: Object to form.

23 THE WITNESS: I don't
24 recall.

1 BY MR. JANUSH:

2 Q. Do you know if -- do you
3 recall whether Noramco produced
4 oxymorphone generally for other
5 manufacturers beyond Endo?

6 A. I do recall that we did
7 produce oxymorphone active pharmaceutical
8 ingredient.

9 Q. Okay. Do you remember about
10 how much of the market Noramco had
11 producing oxymorphone active
12 pharmaceutical ingredient for the
13 non-Endo market in 2011?

14 MR. BARKER: Object to form.

15 THE WITNESS: I didn't
16 have -- I didn't see the marketing
17 information. I don't know the
18 market share. I was not privy to
19 that.

20 BY MR. JANUSH:

21 Q. I'm going to turn your
22 attention to a page that's ending in 58.
23 And specifically I want to address this
24 bullet that I'm circling regarding "the

1 time to process quota requests is the
2 same, it is just that the request leaves
3 the quota group now and is processed
4 through seven layers of review. The
5 order monitoring group was discussed, the
6 suspicious order monitoring group is not
7 reviewing quota requests from
8 manufacturers and reducing quota by the
9 percent diversion they are seeing out in
10 the market. Stacy hinted that we may get
11 a visit regarding our monitoring
12 program."

13 What is this referring to?

14 A. At this time quota request
15 approvals went from just Dr. Sannerud
16 approving quota requests to a longer
17 multi office review.

18 So we had heard that there
19 was an investigation unit in Washington
20 that was also looking at quota requests,
21 and providing input if they are seeing
22 diversion of the products that the quota
23 request was related to. And she was
24 hinting that because of the distributor

1 initiative, and at this time we knew some
2 of the Noramco customers had been asked
3 to go to Washington to review their
4 suspicious order monitoring program and
5 review ARCOS. She was just -- just
6 letting us know that Janssen may be asked
7 to come to Washington as part of the
8 distributor initiative.

9 Q. And do you know which of
10 your Noramco manufacturing customers
11 were -- were asked to go to Washington
12 and review their suspicious order
13 monitoring program with the DEA?

14 A. I just recall one.

15 Q. And who was that?

16 A. KVK.

17 Q. And the statement, "The
18 suspicious order monitoring group is not
19 reviewing quota requests from
20 manufacturers and reducing quota by the
21 percent diversion they are seeing out in
22 the market," did this concern the Noramco
23 suspicious order monitoring group?

24 A. No. Because we don't ship

1 Schedule IIs to customers that do not
2 have active DEA licenses or procurement
3 quota. So it is a controlled market.
4 And --

5 Q. Keep going.

6 A. So our order monitoring
7 group is focused on those locations that
8 DEA has granted approval to receive our
9 active pharmaceutical ingredient.

10 Q. But this is addressing the
11 suspicious order monitoring group is not
12 reviewing quota requests from
13 manufacturers and reducing quota by the
14 percent of diversion. Who is this
15 referring to, if not Noramco?

16 A. Oh, the suspicious order
17 monitoring group at DEA.

18 Q. Okay.

19 A. Remember I said that there's
20 seven layers of review, and there's an
21 investigation group that looked at ARCOS
22 data as well as other data. And that's
23 what it meant.

24 Q. And then at the bottom, it's

1 addressing attachments. I'm circling it.

2 Do you see that?

3 A. Mm-hmm.

4 Q. And it's the presentation.
5 Charts of Noramco data given to Noramco
6 by Greg Kavanaugh and value stream maps.
7 Do you see that?

8 A. Mm-hmm.

9 Q. Okay. So earlier I
10 addressed the fact that the slideshow or
11 slide deck was presented to the FDA.
12 This is the slide deck, is that right,
13 Noramco products DEA review, October 20,
14 2011? Michele Dempsey, Bill Grubb, Mike
15 Kindergan?

16 A. Yes.

17 MR. BARKER: Object to form.

18 BY MR. JANUSH:

19 Q. Is this -- is this the slide
20 deck that -- that I was speaking to
21 earlier?

22 A. This looks like the slide
23 deck.

24 Q. Okay. And I want to jump to

1 Page 2 of the slide deck where you, Bill
2 Grubb and Mike Kindergan have addressed
3 Oxycodone. Do you see that?

4 A. Yes.

5 Q. And here, you are addressing
6 market observations, are you not?

7 A. This is data that Bill Grubb
8 presented in regards to the market.

9 Q. And specifically addressing
10 items such as, "Purdue's volume dropped
11 by 12 percent year over year based on
12 June IMS data."

13 Did I read that right?

14 A. Yes.

15 Q. And that, "IR market growth
16 is still very strong."

17 Read that right?

18 A. Yes.

19 Q. And that, "Noramco customers
20 are growing faster than the market."

21 Do you see that?

22 A. Yes.

23 Q. And in this grid it's
24 addressing, in the center, 2011 oxy base,

1 2011 oxy total market, and 2011 oxy
2 immediate release total; is that right?

3 A. Yes.

4 Q. And specifically where it
5 says, "U.S. market 63 tons," under total
6 2011 oxy market, that's referring to
7 total quota authorized for Oxycodone for
8 the U.S. market; is that right?

9 A. No.

10 Q. What's it referring to?

11 A. That is the equivalent
12 active pharmaceutical kilogram quantity
13 that's available for the market.

14 Q. Right. I think we're saying
15 the same thing. Maybe I said it --

16 A. No. The aggregate
17 production quota was a larger number.

18 Q. Okay. So why don't you
19 explain the difference in layman's terms
20 then, the difference between the 63 tons
21 U.S. market and the aggregate production
22 quota.

23 A. Aggregate production quota
24 is the amount of quota that DEA has

1 identified that is needed to produce to
2 support exports, research, as well as
3 medical need. So it is granted to the
4 manufacturers of active pharmaceutical
5 ingredients. And the quota is based on
6 the first isolation step of the -- of the
7 drug product.

8 So the first time that
9 oxycodone is isolated, that is the
10 production quota that you're granted.
11 But it goes down to further processing.
12 You know, there's purification steps,
13 there's particle sizing steps. And
14 during this additional processing you do
15 lose more material. So what you actually
16 get, you may have a quota grant of
17 100 kilos, but you may only get 80 at the
18 end that is available for the formulator.

19 And then the formulator
20 receives that 80 kilos, and then they
21 formulate, and they have maybe 20 percent
22 losses. So that's why I said this number
23 is lower than what the total aggregate
24 is, because by the time the formulator is

1 done and it's packaged ready for the
2 patient, it's down to that which is based
3 on IMS data. And it's -- it doesn't
4 include the research or export quantities
5 of Oxycodone as well.

6 Q. So this number, 63 tons, is
7 after processing, this is how much -- how
8 many tons of Oxycodone made it to market?

9 A. That is the -- I'm believing
10 it's the IMS data that said it made it to
11 the market.

12 Q. Okay.

13 A. But there is other -- you
14 know, like I said, there's export and
15 research, so...

16 Q. And then going down two
17 boxes, it says, "Share: Total market,
18 51 percent." Is this referring to
19 Noramco's share of the total market of
20 oxycodone?

21 MR. BARKER: Object to form.

22 THE WITNESS: I believe that
23 is what -- I believe -- it's been
24 a while. But I believe that's

1 what Bill was saying.

2 BY MR. JANUSH:

3 Q. Okay. And earlier I asked
4 you about insights into Noramco's market
5 share. And you said that you didn't have
6 access to that data. Do you recall that?

7 A. I know that I was present in
8 the room when this data was reviewed.
9 But in my role I didn't need to know it,
10 so I didn't retain that knowledge.

11 Q. And then in this -- the
12 bottom of the slide, "Noramco production
13 affects the entire IR market."

14 Do you see that?

15 A. Yes.

16 Q. What was meant by that?

17 MR. BARKER: Object to form.

18 THE WITNESS: I don't
19 recall.

20 BY MR. JANUSH:

21 Q. Might it have been that
22 Noramco had 51 percent of the total
23 oxycodone raw API market and, therefore,
24 Noramco's production affects the entire

1 IR market?

2 MR. BARKER: Object to form.

3 THE WITNESS: I don't
4 recall. It could have meant many
5 things. It could have meant
6 production reliability. I don't
7 recall.

8 BY MR. JANUSH:

9 Q. Now, I'm going to move to
10 the slide marked Page 4, Slide 4. And it
11 ends in Bates number 963.

12 And here, on oxycodone quota
13 considerations, your group was telling
14 the DEA, "Noramco has virtually all of
15 the immediate release market excluding
16 Covidien source dosages."

17 Is that right?

18 MR. BARKER: Object to form.

19 THE WITNESS: My group,
20 which was DEA compliance, was not
21 telling them. Sales and marketing
22 was telling DEA.

23 BY MR. JANUSH:

24 Q. Well, you were part of quota

1 oversight in 2011 for Noramco, weren't
2 you?

3 A. I managed the quota
4 submission process at Noramco at this
5 time.

6 Q. And you -- when I say group,
7 you and Bill and --

8 A. Mike and --

9 Q. -- and Mike were a group of
10 three that were presenting Noramco quota
11 considerations to the DEA in October of
12 2011; true or false?

13 A. I was present at this
14 meeting where sales and marketing
15 presented this information to DEA for
16 their consideration in the aggregate
17 production quota process.

18 Q. But it's not just sales and
19 marketing. You provided the credibility
20 from the Noramco side of the fence
21 because you were involved in setting
22 quota for Noramco, right?

23 MR. BARKER: Object to form.

24 THE WITNESS: I did not set

1 quota. I -- based on the
2 production plan and the demand,
3 when you're in the API quota
4 manufacturing process, you don't
5 know if the demand is accurate
6 because it's based on what our
7 customers get, and we don't have
8 visibility to their quota grants.

9 So we have these meetings
10 where we're meeting with DEA,
11 presenting what we think we know
12 what the market is going to be
13 because we're getting these demand
14 signals from these customers. And
15 these meetings were used to, you
16 know, to let DEA know, here are
17 some of the customers, here is the
18 feedback. And, you know, keep
19 this -- consider this when you're
20 reviewing our 2012 request for
21 quota. This is what our customers
22 are telling us.

23 BY MR. JANUSH:

24 Q. Right. And going back to my

1 question that I actually asked you, you
2 were involved in the meeting because you
3 were involved in quota issues on behalf
4 of Noramco, weren't you?

5 MR. BARKER: Object to form.

6 THE WITNESS: The word
7 "quota issues" is what has me
8 confused. I managed the quota
9 process, which means going out,
10 doing the year-end reporting,
11 getting the quota that we are to
12 produce, and then engaging DEA if
13 we need more current year quota.

14 BY MR. JANUSH:

15 Q. Now, I'm going to move over
16 to hydrocodone. This is Slide 12, ending
17 in Bates number 971. I'm going to
18 address the market observations. And
19 here too, as with oxy, you're presenting
20 to the DEA that Noramco customers gaining
21 market share from Covidien.

22 Do you see that?

23 MR. BARKER: Object to form.

24 THE WITNESS: Mm-hmm. Yes,

1 I do see that.

2 BY MR. JANUSH:

3 Q. And part of your
4 presentation also entailed this bold
5 bullet, "Noramco is a key supplier,
6 hydrocodone to the market."

7 Do you see that?

8 MR. BARKER: Object to form.

9 THE WITNESS: I see that.

10 BY MR. JANUSH:

11 Q. Did you agree with that when
12 you met with DEA in 2011?

13 A. Did I agree with that?

14 Q. That statement.

15 A. Personally?

16 Q. There's data on this page,
17 right?

18 A. It appears that the demand
19 shows that, based on the IMS sales, we
20 did have a market share.

21 Q. And, in fact, Noramco's
22 market share of the -- as expressed in
23 base product in June of 2011, was
24 43 percent of 38.5 tons of hydrocodone in

1 the market; is that right?

2 MR. BARKER: Object to form.

3 THE WITNESS: That is what
4 the table states.

5 BY MR. JANUSH:

6 Q. Do you try and be accurate
7 when presenting Noramco information to
8 the DEA?

9 MR. BARKER: Object to form.

10 THE WITNESS: Sales and
11 marketing provided -- I know that
12 they did have IMS data. But if
13 this is accurate, I don't know.

14 BY MR. JANUSH:

15 Q. What does it mean, "Share
16 of" -- "share - available market" with
17 the asterisk here? What does that mean?

18 MR. BARKER: Object to form.

19 THE WITNESS: I don't
20 recall.

21 BY MR. JANUSH:

22 Q. Now, I want to shift to
23 oxymorphone. And that's Slide 15. And
24 it ends in 974.

1 Do you see that?

2 A. Yes.

3 Q. And the market summary
4 presented by your group to the DEA was,
5 "Endo's Opana is growing rapidly,
6 54 percent. Many generics to Opana brand
7 poised to launch in September of 2012."

8 Did I read that market
9 summary correct?

10 A. Yes.

11 Q. Okay. And API supplier
12 shifts is addressed; is that right?

13 A. Yes.

14 Q. And the first hyphen or note
15 is, "Noramco produces a low ABUG active
16 ingredient."

17 What does that mean?

18 MR. BARKER: Object to form.

19 THE WITNESS: It is an
20 abbreviation for a long impurity.

21 BY MR. JANUSH:

22 Q. For a what?

23 A. Impurity. So what they are
24 saying is our oxymorphone is low

1 impurity. The specific impurity which I
2 don't recall what ABUK stands for.

3 Q. Okay. And it's the next two
4 notes that I'm going to specifically
5 focus on.

6 "Unexpectedly Noramco has
7 received increase from virtually every
8 generic who originally formulated with
9 Mallinckrodt material. API demand went
10 from near 60 kilograms to near
11 600 kilograms overnight and now includes
12 nine companies."

13 Is that right?

14 MR. BARKER: Object to form.

15 THE WITNESS: That is what
16 the slide says.

17 BY MR. JANUSH:

18 Q. Okay. Do you recall who the
19 other -- who the generics were that were
20 reformulating originally with
21 Mallinckrodt that turned to Noramco for
22 oxymorphone?

23 A. I do not recall.

24 Q. Where would information

1 concerning that API supplier shift be
2 stored?

3 MR. BARKER: Object to form.

4 THE WITNESS: That would be
5 in the sales and marketing files
6 at Noramco.

7 BY MR. JANUSH:

8 Q. Do you know -- do you know
9 why Noramco received inquiries from
10 virtually every generic manufacturer or
11 generic seller who was originally --
12 originally formulating with Mallinckrodt?

13 MR. BARKER: Object to form.

14 THE WITNESS: I don't
15 recall.

16 BY MR. JANUSH:

17 Q. I'm going to turn to
18 Slide 23. There's a summary of requests
19 at 982. Bates number ending in 982.

20 And -- and here are a
21 summary of requests that were being made
22 to the DEA; is that right?

23 A. That is what this table was,
24 yes.

1 Q. Okay. And so for Oxycodone,
2 you were asking "include exports and
3 inventory for customer qualification in
4 the 2012 aggregate production quota"; is
5 that right?

6 MR. BARKER: Object to form.

7 THE WITNESS: Yes.

8 BY MR. JANUSH:

9 Q. And, "For hydrocodone
10 include second site qualification quota
11 in the 2012 aggregate production quota."

12 What does that mean?

13 MR. BARKER: Object to form.

14 THE WITNESS: When you want
15 to produce an active
16 pharmaceutical at a new location,
17 you need to have development
18 validation quota. This is quota
19 that is not readily available to
20 the patient because you have to
21 demonstrate through three to four
22 batches that you can produce the
23 active pharmaceutical to
24 specifications and you

1 consistently can make it. And
2 then that material gets placed on
3 hold until customer filings get
4 approved by FDA.

5 So it's not quota that is
6 going to be consumed for medical
7 year in the year in which it's
8 produced.

9 BY MR. JANUSH:

10 Q. Got it. Thank you for that
11 explanation. I'm going to move off this
12 document and move on to Exhibit 3.

13 (Document marked for
14 identification as Exhibit
15 Dempsey-3.)

16 BY MR. JANUSH:

17 Q. This is a document from
18 trade analytics titled Managed Market
19 Summit, October 18, 2012. Incidentally,
20 do you know what the trade analytics
21 group does at Johnson & Johnson or
22 Janssen?

23 MR. BARKER: Object to form.

24 THE WITNESS: No, I'm not

1 aware.

2 BY MR. JANUSH:

3 Q. Okay. Did you ever deal
4 with trade analytics?

5 A. Not in the past, no.

6 Q. It's fair. I'm just going
7 to ask you some questions about it.

8 MR. BARKER: Before you ask
9 your next question, do you happen
10 to have the Bates that is
11 associated with this native file?

12 MR. JANUSH: My apologies, I
13 should have read that into the
14 record.

15 Yes, it's not on the file.
16 It's on my folder. It's
17 JAN-MS-01117436. And I believe
18 this came from the custodial file
19 of Paul Lowman, L-O-W-M-A-N.

20 BY MR. JANUSH:

21 Q. Do you know who Paul Lowman
22 is? No?

23 THE REPORTER: Please answer
24 out loud.

1 THE WITNESS: No.

2 BY MR. JANUSH:

3 Q. All right. Okay. I'm using
4 this more so for informational purposes.
5 This isn't to cross-examine you over this
6 document. I want to establish some
7 concepts in this document. And then I'll
8 address them later in your deposition as
9 it concerns documents in your custodial
10 file, okay?

11 A. Okay.

12 Q. Just wanted to give you that
13 background as to why I'm presenting you
14 with this.

15 So this is trade analytics.
16 And it appears to be addressing in the
17 header of Page 2 of the slide deck. "In
18 2011, Janssen recognized need to better
19 understand the distribution of our
20 products."

21 Did I read that right?

22 A. Yes.

23 Q. Okay. And at the bottom,
24 it's addressing this concept of a bullet

1 that just says leverage new data sources,
2 right? And then here on Page 3, or
3 Slide 3, it's addressing -- trade
4 analytics is addressing, "In 2005,
5 wholesalers began sending us information
6 on their shipments to qualify for a
7 distributor performance agreement, a
8 DPA."

9 So my question to you first
10 is, have you heard of this concept of a
11 distributor performance agreement in your
12 various roles with Johnson & Johnson
13 entities?

14 A. Not in my compliance role.
15 I've never had visibility to this
16 performance agreement.

17 Q. Okay. And key information
18 that we received, the we being trade
19 analytics it appears, is 852, wholesalers
20 inventory and total sales out to their
21 customers. Do you see that?

22 A. Yes.

23 Q. Do you have an understanding
24 as you sit here today as to what 852 data

1 is?

2 MR. BARKER: Object to form.

3 THE WITNESS: I have been
4 told it allows our trade customers
5 to see the level of days of
6 supply, or weeks of supply, I'm
7 not sure which, of all of our
8 Janssen products.

9 BY MR. JANUSH:

10 Q. And the next bullet is
11 addressing 867 data. And it states,
12 "Wholesalers' total sales out to their
13 customers, broken out by outlet," and in
14 parens, (i.e., retail pharmacies,
15 hospitals, long-term care, clinics, et
16 cetera, last points of care in the supply
17 chain where product is shipped prior to
18 delivering to the patients).

19 Do you see that?

20 A. Mm-hmm.

21 Q. Do you have an understanding
22 of what 867 data is as it concerns
23 wholesalers' sales?

24 MR. BARKER: Object to form.

1 THE WITNESS: I -- I do
2 understand now 867. We -- there
3 are people in the planning and
4 trade that does provide this data
5 to us occasionally. So yes, I am
6 aware of 867.

7 BY MR. JANUSH:

8 Q. And what is -- why is 867
9 data provided from trade to compliance
10 occasionally?

11 A. For order monitoring. If we
12 have an order that is questionable, we --
13 our process involves planning, trade and
14 customer service reaching out to the
15 customer, obtaining information to
16 justify the questionable order demand
17 change. And so 867 data can be provided
18 to -- as part of the investigation.

19 Q. And the last bullet is
20 addressing 844 and 849. "Chargeback data
21 which identifies how much a vendor
22 qualifies for rebates."

23 Do you see that?

24 A. Yeah.

1 Q. And do you have an
2 understanding of what chargeback data or
3 844, 849 data is?

4 A. I never heard of the word
5 844, 849. But in -- after the
6 Mallinckrodt incident, I did learn about
7 chargeback data.

8 Q. And did you only learn about
9 chargeback data after the Mallinckrodt
10 incident?

11 Are you referring to the
12 2017 DEA citation with Mallinckrodt?

13 A. Yes.

14 Q. Okay. And so after some
15 point in time in 2017 when the DEA
16 cracked down on Mallinckrodt for not
17 using its chargeback data to figure out
18 how much drugs their end purchasers
19 were -- were obtaining, that's the first
20 time you learned about chargeback data?

21 A. That's the first time I
22 asked if we had the chargeback data, and
23 then I received the data. And we tried
24 to analyze it. But it was missing, it

1 was blinded and was missing some
2 information that we couldn't do a full
3 analysis.

4 Q. Okay. And -- and that leads
5 to the very next slide, this concept of
6 blinded data and unblinded data.

7 So trade analytics is
8 addressing, on October 18, 2012, in this
9 slide deck, "However, wholesalers provide
10 partial 867 information at the zip code
11 level and this limits our ability to
12 generate insights."

13 Do you see that?

14 A. I do.

15 Q. And the next statement
16 following that header is, "With the help
17 of outside data vendors, we are able to
18 unblind and unblock this information.
19 Provides visibility to inventory at
20 retail chain pharmacies. Provides
21 visibility of shipments to individual
22 retail stores. This level of visibility
23 was not available prior to 2011."

24 Did I read that page

1 correctly?

2 A. Yes.

3 Q. Okay. In October 2012, did
4 you know that your company had the
5 ability to unblind and unblock the sales
6 it was making to wholesalers to obtain
7 visibility of your inventory at
8 individual retail stores?

9 MR. BARKER: Object to form.

10 THE WITNESS: In 2012, no.

11 BY MR. JANUSH:

12 Q. When did you first learn
13 that as the director of controlled
14 substance compliance?

15 MR. BARKER: Object to form.

16 THE WITNESS: In 2017.

17 BY MR. JANUSH:

18 Q. Until sitting here for your
19 deposition and being presented with this
20 trade analytics document that's
21 addressing how trade was unblinding and
22 unblocking wholesalers' data with the
23 help of outside vendors, had you ever
24 heard that this was happening --

1 MR. BARKER: Object.

2 BY MR. JANUSH:

3 Q. -- before today?

4 MR. BARKER: My apologies.
5 Object to form.

6 THE WITNESS: I knew in the
7 fall of 2017 that the reason why
8 trade analytics wasn't familiar,
9 the Commercial Center of
10 Excellence was obtaining
11 IntegriChain data for our brand
12 products that did not include our
13 established products that covered
14 Duragesic.

15 So I did find out at the end
16 of 2017 that we were -- that we
17 were using IntegriChain for some
18 of our products.

19 BY MR. JANUSH:

20 Q. But not for Duragesic; is
21 that right?

22 A. Right.

23 Q. And not using IntegriChain
24 for Nucynta during the years that Nucynta

1 was sold by Janssen from 2009 through
2 2015; is that right?

3 MR. BARKER: Object to form.

4 THE WITNESS: I did not know
5 that this data was available. No,
6 I did not know.

7 BY MR. JANUSH:

8 Q. So I didn't -- I appreciate
9 your answer that you didn't know this
10 data was available, and actually being
11 purchased by outside vendors at Johnson &
12 Johnson. I'm addressing a different
13 question. I'm addressing that throughout
14 all of the time -- I'll ask it totally
15 differently.

16 Throughout all of the time
17 that Duragesic was being sold in brand or
18 generic format, you didn't know until
19 2017 that another division within Johnson
20 & Johnson was using outside data vendors
21 to unblind and unblock sales to
22 wholesalers; is that right?

23 MR. BARKER: Object to form.

24 THE WITNESS: At that time

1 we had a compliance program with
2 our order monitoring where we
3 delivered what DEA asked for. And
4 up until 2017, DEA had never
5 mentioned the requirement that
6 they wanted us to look at
7 chargeback or downstream
8 analytics.

9 MR. JANUSH: Move to strike
10 as nonresponsive.

11 BY MR. JANUSH:

12 Q. You understand that wasn't
13 my question, right?

14 A. Yes.

15 Q. Okay. Let's answer my
16 question.

17 So my question was,
18 throughout all of the time that Duragesic
19 was being sold in brand or generic
20 format, you didn't know until 2017 that
21 another division within Johnson & Johnson
22 was using outside data vendors to unblind
23 and unblock sales to wholesalers; is that
24 right?

1 MR. BARKER: Object to form.

2 THE WITNESS: Yes.

3 BY MR. JANUSH:

4 Q. Moving to Slide 5. Title or
5 header of the slide reads, "New unblinded
6 data allowed Janssen to gain a number of
7 new insights."

8 Did I read that right?

9 A. Yes.

10 Q. First bullet, "Shipment
11 volume to pharmacy chains. For example,
12 Nucynta ER sales to Walgreens in 2012
13 year-to-date 31,354 units, and current
14 WAC dollars" -- W-A-C dollars --
15 "year-to-date are \$9.76 million."

16 Do you see that?

17 A. Yes, I do.

18 Q. So although you're the
19 director of controlled substance
20 compliance, you weren't getting this
21 detail, this information that new
22 unblinded data was able to show Nucynta
23 ER sales to Walgreens in year 2012?

24 MR. BARKER: Object to form.

1 THE WITNESS: No.

2 BY MR. JANUSH:

3 Q. And earlier you said that
4 you were aware that in 2017 that another
5 division within Johnson & Johnson was
6 getting this data. But that it was not
7 getting this data concerning Duragesic
8 and Nucynta, right?

9 A. At the time that I learned
10 about this IntegriChain data, it was only
11 for key products. I don't know if prior
12 to 2017 they did include Duragesic and
13 Nucynta. But at the time that I was -- I
14 learned of this, Duragesic was not
15 included, and Nucynta was no longer a
16 product.

17 Q. Okay. But in 2012, Nucynta
18 was a product, right?

19 A. Yes.

20 Q. Not just Nucynta IR, Nucynta
21 ER was as well, right?

22 A. I'm trying to --

23 MR. BARKER: Object to form.

24 THE WITNESS: I don't know

1 when -- I forget when we exactly
2 launched the ER.

3 BY MR. JANUSH:

4 Q. I'm going to represent to
5 you that Nucynta ER was launched 2011.
6 But you don't have to trust me on that.

7 A. Okay.

8 Q. I'm just making that --

9 A. It says it here as well.

10 Q. -- representation. Okay.

11 So this is showing --
12 depicting that unblinded data allowed
13 Janssen to see Nucynta ER sales to
14 Walgreens in 2012. And what are current
15 WAC dollars? Do you know what WAC means?

16 MR. BARKER: Object to form.

17 THE WITNESS: No.

18 BY MR. JANUSH:

19 Q. But current dollars year to
20 date looks like \$9.76 million is listed
21 here; is that right?

22 MR. BARKER: Objection to
23 form.

24 THE WITNESS: That's what

1 this says.

2 BY MR. JANUSH:

3 Q. Okay. And yet in 2012, your
4 compliance group wasn't getting this
5 unblinded data to see where your drugs
6 were winding up at the retail level, were
7 you?

8 A. No.

9 Q. We talked earlier about
10 unblinded 867 data. Do you remember
11 that?

12 A. Yes.

13 Q. And can you remind me what
14 867 data is?

15 A. That is the data from the
16 wholesaler to the pharmacy.

17 Q. Okay. And this is
18 showing -- stating from the trade
19 analytics group, "Unblinded data also
20 allows us to answer a number of questions
21 from the SCG trade group and marketing
22 teams."

23 What's the SCG trade group?
24 That's the supply chain group, isn't it?

1 MR. BARKER: Object to form.

2 THE WITNESS: No, I don't

3 believe that's -- I don't know

4 what it stands for.

5 BY MR. JANUSH:

6 Q. I'm going to represent to

7 you that I've only seen SCG as referring

8 to supply chain group. Do you know --

9 have you seen any other group listed at

10 Janssen with an acronym of SCG?

11 MR. BARKER: Object to form.

12 THE WITNESS: I just know

13 them as the trade folks, the trade

14 group.

15 BY MR. JANUSH:

16 Q. There is a supply chain

17 distribution group within JOM, isn't

18 there?

19 MR. BARKER: Object to form.

20 THE WITNESS: They are --

21 JOM is part of the organization,

22 the logistics organization within

23 J&J.

24 BY MR. JANUSH:

1 Q. And logistics refers to --

2 A. Yes.

3 Q. -- supply chain, doesn't it?

4 A. Yes.

5 Q. So I'm not pulling this out
6 of left field when I say there's a supply
7 chain group within J&J, right?

8 MR. BARKER: Object to form.

9 THE WITNESS: I don't -- I
10 don't know what the SC stands for
11 in here. It could be strategic.
12 But I don't know what it stands
13 for.

14 BY MR. JANUSH:

15 Q. Okay. But that's not my
16 question. I'm making the comment that
17 SCG, you've heard of the term supply
18 chain group before, haven't you?

19 MR. BARKER: Object to form.

20 THE WITNESS: No, I have not
21 heard the word "supply chain
22 group." That is why.

23 BY MR. JANUSH:

24 Q. And it's stating here that,

1 "Insights around purchasing behavior of
2 individual outlets can resolve demand
3 issues and help build demand strategies.
4 For example, which high decile pharmacies
5 should be targeted for Xarelto DVT at
6 launch."

7 Do you see that?

8 A. Yes.

9 Q. And I'm going to skip. But
10 it also says at the lower two bullets,
11 the last two, "How long will the
12 inventory with CVS last?"

13 Do you see that?

14 A. Yes.

15 Q. And the last bullet, "What
16 mix of product strengths are stocked by
17 an outlet?"

18 Do you see that?

19 A. Yes.

20 Q. So unblinded data, looks
21 like, can be pretty helpful in gaining
22 some insights into the individual
23 outlets; is that right?

24 MR. BARKER: Object to form.

1 THE WITNESS: Yes.

2 BY MR. JANUSH:

3 Q. And now I want to turn to
4 Slide 14. And this is addressing the
5 stocking tool territory level. "For the
6 first time our sales reps know which
7 pharmacies have purchased and which high
8 decile pharmacies have not purchased our
9 products."

10 Do you see that?

11 A. Yes.

12 Q. And Nucynta ER and Nucynta
13 are being shown along with Xarelto as the
14 current 13-week example; isn't that
15 right?

16 MR. BARKER: Object to form.

17 BY MR. JANUSH:

18 Q. I circled it to make it
19 easier for you to see.

20 A. Yes, I see.

21 Q. Okay. And this is looking
22 at the Denver, Colorado region. District
23 name, Kingman, Arizona. Territory name,
24 Phoenix, North Arizona.

1 Am I reading that right?

2 A. Yes, you are.

3 Q. And it's showing that
4 Johnson & Johnson had -- and Janssen had
5 the ability to see down to the individual
6 pharmacy level, like the first example,
7 CVS 9339. That's a store number. And
8 C -- let's go to the maroon in the
9 middle, Nucynta ER decile, Nucynta ER
10 stocking status for the rolling 13 weeks.

11 Do you see this? I'm
12 circling in red.

13 A. Yes.

14 Q. Yet, you in your compliance
15 group wasn't getting this stocking tool
16 data while you were looking at suspicious
17 order monitoring in 2012, were you?

18 A. No, we were not.

19 Q. It might have been useful to
20 see which pharmacies were stocking at a
21 higher volume than others in a zip -- in
22 a given zip code, right?

23 MR. BARKER: Object to form.

24 BY MR. JANUSH:

1 Q. It certainly wouldn't have
2 been useless, right?

3 MR. BARKER: Object to form.

4 THE WITNESS: We have a very
5 transparent relationship with DEA.
6 And if DEA was noting any unusual
7 activity, they would have
8 contacted us. And we were
9 delivering -- our order monitoring
10 program was delivering what DEA
11 wanted to see, and they were not
12 asking us to provide this
13 information to them at the time.

14 BY MR. JANUSH:

15 Q. Ma'am, what was my question?

16 A. You were asking me would
17 this information have been relevant for
18 our order monitoring program. And I'm
19 saying during Nucynta, that we were not
20 asked to provide this information to DEA.

21 MR. JANUSH: So I'm going to
22 move to strike as nonresponsive.

23 BY MR. JANUSH:

24 Q. I asked you it might have

1 been useful to see which pharmacies were
2 stocking at a higher volume than others
3 in a given zip code, right?

4 MR. BARKER: That's the
5 second time that you have said
6 that as though her answer wasn't
7 responsive to your question. It
8 was. You asked her --

9 MR. JANUSH: No speaking
10 objections under our rules. You
11 may make your record by saying
12 objection and preserve it. But
13 there's no speaking objections
14 under our rules.

15 MR. BARKER: Well, in that
16 case, then I object to the motion
17 to strike.

18 MR. JANUSH: I don't want to
19 get the court on the phone.

20 MR. BARKER: And I don't
21 want you to get the court on the
22 phone either.

23 MR. JANUSH: Okay. Then
24 you --

1 MR. BARKER: But you -- you
2 are suggesting something that
3 isn't true.

4 MR. JANUSH: Please don't
5 muddy up my record. There are
6 rules here. We all operate by
7 them. I'll be similarly
8 respectful to you and just say
9 objection and preserve our record
10 for later on at the court level.

11 BY MR. JANUSH:

12 Q. I asked the question. My
13 question was, "It might have been useful
14 to see which pharmacies were stocking at
15 a higher volume than others in a given
16 zip code," right?

17 A. No.

18 Q. Are you sure about that?

19 A. Yes.

20 Q. So as an example to follow
21 up my question, if you had data at your
22 disposal that trade analytics had in
23 2012, and hypothetically could see that a
24 given pharmacy was buying a -- was

1 receiving from one of your wholesaler
2 customers a significant amount of Nucynta
3 in a particular zip code, that wouldn't
4 have been a red flag for you?

5 MR. BARKER: Object to form.

6 THE WITNESS: DEA expected
7 the wholesalers to be monitoring
8 those levels. And since we know
9 our customers and we do the due
10 diligence with the wholesaler,
11 part of the due diligence is
12 ensuring that our products are
13 covered in their suspicious order
14 monitoring program. And if there
15 was a pharmacy with unusual
16 levels, they would have flagged it
17 and done the investigation.

18 BY MR. JANUSH:

19 Q. So that information would
20 have been entirely useless to you. Is
21 that what you're saying?

22 MR. BARKER: Object to form.

23 THE WITNESS: Yes. As
24 long -- because they had their

1 suspicious order monitoring
2 program in place.

3 BY MR. JANUSH:

4 Q. This information that I'm
5 talking about concerning specific
6 pharmacy retail level data would fall
7 under the rubric of knowing your
8 customers' customers, right?

9 MR. BARKER: Object to form.

10 THE WITNESS: That would be
11 what it would be termed as after
12 the 2017 notification, knowing the
13 downstream customers of your
14 products.

15 BY MR. JANUSH:

16 Q. But you heard about this
17 concept from other manufacturers
18 regarding the need to know your
19 customers' customers as early as 2012,
20 didn't you?

21 MR. BARKER: Object to form.

22 THE WITNESS: I did not hear
23 from other manufacturers this need
24 to know your customer beyond the

1 wholesaler. I didn't engage
2 manufacturers to know that
3 downstream data.

4 BY MR. JANUSH:

5 Q. Are you sure about that?

6 A. Well, I know Noramco
7 customers, we asked about their SOM
8 program. We had them fill out a
9 questionnaire, do they have a suspicious
10 order monitoring program in place and
11 are -- you know, does it cover our
12 products.

13 Q. You didn't -- you didn't --

14 A. But we didn't go visit and
15 say show me how you do it and the
16 downstream data that they analyze.

17 Q. And when you just said we
18 didn't go visit and say show me how you
19 do it and the downstream data that they
20 analyze, you're referring to we didn't go
21 and visit other manufacturers that were
22 similar to Janssen and visit with them to
23 visit the downstream data; is that right?

24 MR. BARKER: Objection to

1 form.

2 THE WITNESS: We benchmarked
3 with Noramco customers. As part
4 of our due diligence from Noramco,
5 we wanted to understand their
6 suspicious order monitoring
7 program. And so we did reach out
8 to Purdue and Watson to understand
9 what the program involved, the
10 algorithm, the compliance
11 meetings, the due diligence on the
12 wholesalers.

13 BY MR. JANUSH:

14 Q. Purdue is more like Janssen
15 as a manufacturer and seller of product
16 than it is like Noramco, correct?

17 MR. BARKER: Objection.

18 Object to form, I guess.

19 BY MR. JANUSH:

20 Q. In other words, Noramco is
21 making raw opioid products --

22 A. The pharmaceutical
23 ingredients.

24 Q. -- active pharmaceutical

1 ingredients, API, right?

2 A. Yes.

3 Q. And Purdue is, like Janssen,
4 a manufacturer and marketer, a seller, of
5 opioid products, and other products,
6 correct?

7 A. Purdue does formulate and
8 sell products, yes.

9 Q. And markets their opioid
10 products, correct?

11 A. Yes.

12 Q. And Janssen markets its
13 opioid products, right?

14 A. Janssen -- Janssen does have
15 opiate products that I guess were
16 marketed years ago. But I don't recall
17 if their opiates are marketed right now.

18 Q. Earlier you addressed
19 that -- that, on behalf of Noramco, you
20 benchmarked with other manufacturers who
21 make and sell opioid products; is that
22 right?

23 A. Yes.

24 Q. But Noramco was not like a

1 Purdue; Janssen was more like Purdue than
2 Noramco, true or false?

3 MR. BARKER: Object to form.

4 THE WITNESS: Okay.

5 Technically Purdue had an API
6 manufacturer called Rhodes, just
7 like Janssen has an API
8 manufacturer like Noramco. That's
9 why I'm hesitating. So they are
10 both alike, that they had inhouse
11 API manufacturing through
12 formulation and distribution.

13 BY MR. JANUSH:

14 Q. Okay. Noramco doesn't look
15 at red flag issues concerning high
16 prescribing physicians, right?

17 MR. BARKER: Object to form.

18 THE WITNESS: In our -- in
19 our controlled environment we only
20 ship to licensed customers that
21 had procurement -- certificate of
22 procurement quota and a 222 to
23 receive our products.

24 BY MR. JANUSH:

1 Q. What was my question?

2 A. You wanted to know if we
3 used the red flags that the wholesalers
4 to the pharmacies monitor.

5 Q. What's the answer to that
6 question?

7 A. No, Noramco did not have to
8 monitor the red flags to the pharmacies.

9 Q. Okay. Thank you.

10 MR. BARKER: Evan, you've
11 been going nearly two hours. I
12 see you reaching for another
13 document. If you're done with
14 this document, is now a good time
15 for a break?

16 MR. JANUSH: Absolutely.
17 Absolutely.

18 THE VIDEOGRAPHER: Stand by.
19 Remove your microphones.

20 The time is 11:03 a.m. Off
21 the record.

22 (Short break.)

23 THE VIDEOGRAPHER: We are
24 back on the record. The time is

1 11:25 a.m.

2 BY MR. JANUSH:

3 Q. Hello, Ms. Dempsey. I'm
4 going to take you back to Exhibit 3,
5 Slide 3. And it's up on the monitor for
6 you as well. And earlier I had asked you
7 if you were aware in 2012 that Johnson &
8 Johnson or any of its pharmaceutical
9 entities, including Janssen, was
10 purchasing 852 or 867 data from outside
11 vendors. Do you remember that?

12 MR. BARKER: Object to form.

13 THE WITNESS: Yes, I do
14 remember you asking that question.

15 BY MR. JANUSH:

16 Q. And you didn't know in 2012
17 and didn't learn until 2017 that Janssen
18 had been acquiring 852 and 867 data
19 concerning wholesalers' inventory or
20 wholesalers' total sales out to their
21 customers; is that right?

22 MR. BARKER: Object to form.

23 THE WITNESS: No. As I
24 explained before, I was aware of

1 852 and 867 from the wholesaler
2 perspective, and we used that data
3 in our order monitoring program as
4 needed. But I did not know 844,
5 849 at the time. I heard the
6 terminology 867 and 852 by some of
7 the planners at JOM. But I did
8 not know what those meant until
9 later on.

10 BY MR. JANUSH:

11 Q. When you say, "We used that
12 data as needed," the 852 and 867 data,
13 how did you use that data as needed?

14 A. As I explained before, when
15 an order, a controlled substance order,
16 goes through the order monitoring
17 program, if it is deemed to be
18 questionable, customer service planning
19 is involved in reaching out to the
20 customer to understand why it is not a
21 typical order. And this data is used
22 to -- in some cases, as justification to
23 show that downstream inventory is low and
24 it required additional information --

1 this order was justified for release.

2 Q. Okay. And I asked you
3 earlier in this deposition, quote, "In
4 October 2012" -- and this was asked
5 before you took your break -- "did you
6 know that your company had the ability to
7 unblind and unblock the sales it was
8 making to wholesalers to obtain
9 visibility of your inventory at
10 individual retail stores?" And your
11 answer was, "In 2012, no."

12 Do you remember being asked
13 that and giving that answer?

14 A. Yes, I do.

15 Q. And I asked you, "When did
16 you first learn that as the director of
17 controlled substance compliance?" And
18 you said, "In 2017."

19 Do you remember being asked
20 that question and giving that answer?

21 A. Yes, I do.

22 Q. And I said, "Until sitting
23 here for your deposition and being
24 presented with this trade analytics

1 document that's addressing that trade was
2 unblocking and unblinding wholesalers'
3 data with the help outside vendors, had
4 you ever heard that this was happening
5 before today?" And you said, "I knew in
6 the trade analytics" -- this is -- "I
7 knew in the trade analytics -- wasn't
8 familiar being the Commercial Center of
9 Excellence was obtaining IntegriChain
10 products for our brand products. That
11 did not include our established products
12 that covered Duragesic. So I did find
13 out at the end of 2017 that we were using
14 IntegriChain for some of our products."

15 And I asked, "But not for
16 Duragesic?" And you answered, "Right."

17 Do you remember being asked
18 that question and answering as such?

19 A. Yes.

20 Q. And I then asked, "And not
21 using IntegriChain for Nucynta during the
22 years that Nucynta was sold by Janssen
23 from 2009 through 2015; is that right?"

24 And you said, "I did not know that this

1 data was available. No, I did not know."

2 Do you remember being asked
3 that question and giving that answer?

4 A. Yes.

5 Q. Okay. Can you appreciate
6 that your answer to my question at the
7 outset of -- circling back from the long
8 break that we just took, is inconsistent
9 with the answers that you gave earlier?

10 MR. BARKER: Object to the
11 form.

12 THE WITNESS: No. As I
13 explained previously, I heard the
14 planners speak to 852 and 867
15 data. I did not know what that
16 means until -- in 2017 when it was
17 communicated about understanding
18 downstream data. And then it was
19 explained in more detail. And we
20 realized for our Duragesic in
21 2017, we no longer -- I don't know
22 if we had it in the past, but for
23 Duragesic, we did not have the
24 unblinded data from IntegriChain.

1 So -- so I've heard, like I
2 mentioned before, 867 and 852 were
3 terms used by our planners in
4 trade while we were investigating
5 questionable orders. But I did
6 not know that we could go
7 downstream for some of our
8 products that -- that there was
9 some downstream data, because I
10 was never asked to provide that
11 data to DEA.

12 BY MR. JANUSH:

13 Q. You were the director of
14 controlled substance compliance, though,
15 from March 2012 forward, correct?

16 A. Yes.

17 Q. And as the director of
18 controlled substance compliance, you
19 didn't know that -- what 852 and 867 data
20 could or could not be used to investigate
21 orders?

22 A. No, I know what data DEA
23 requested us to provide when they came in
24 to do their inspections and when they

1 reviewed our suspicious order monitoring
2 program.

3 Matter of fact, we sat down
4 with DEA in July of 2013 and reviewed our
5 program. We asked for recommendations or
6 input, and they were happy with our --
7 they just had no recommendations at that
8 time.

9 MR. JANUSH: Move to strike
10 as nonresponsive.

11 BY MR. JANUSH:

12 Q. My question was, and as the
13 director of controlled substance
14 compliance, you didn't know that 852 and
15 850 -- what 852 and 867 data could or
16 could not be used to investigate orders?

17 MR. BARKER: Object to form.

18 MR. JANUSH: That was my
19 question.

20 THE WITNESS: As the
21 compliance leader, we want to
22 provide DEA with the information
23 they request. And in our order
24 monitoring program we had a

1 process where all the orders were
2 investigated that were
3 questionable, and either the
4 customer provided data or the
5 planners provided the data.

6 In this compliance role I
7 did not have to know down to the
8 detail of what this data was.
9 There was a DEA compliance manager
10 that understood what this
11 information was and provided the
12 release of them if it deemed
13 justified.

14 BY MR. JANUSH:

15 Q. Who was that?

16 A. At the time it was Mike
17 Levitt.

18 Q. And what time was that?

19 A. 2012 through 2016.

20 Q. Okay. And you as the
21 director of controlled substance
22 compliance didn't have any -- a specific
23 understanding of what 852 and 867 data
24 was between 2012 and 2017 until the DEA

1 cracked down on Mallinckrodt?

2 A. I knew that 867 and 852
3 provided information on the wholesaler
4 inventory. What they have there, and
5 what's going out, so that we can evaluate
6 if their local distribution center
7 inventory is consistent with historical.
8 Which is part of our due diligence was to
9 know our customer which was the
10 wholesaler.

11 Q. But you just testified
12 moments ago, "But I did not know that we
13 could go downstream for some of our
14 products, that there was some downstream
15 data, because I was never asked to
16 provide that data to the DEA."

17 Didn't you just testify as
18 such?

19 MR. BARKER: Object to form.

20 THE WITNESS: I provided DEA
21 what they expected us to provide,
22 which was know our customer, which
23 was the wholesaler. And when
24 orders were being released,

1 there -- if there was questionable
2 orders, we had to do the
3 investigation and engage the
4 customer for justification.

5 BY MR. JANUSH:

6 Q. I'm addressing the fact that
7 you personally did not know that you
8 could go downstream for some of your
9 products, and you have testified that you
10 did not believe you had data on Nucynta
11 or Duragesic concerning 852 and 867 data.

12 MR. BARKER: Objection.

13 BY MR. JANUSH:

14 Q. Do you recall providing such
15 testimony?

16 MR. BARKER: My apologies.
17 Object to form.

18 THE WITNESS: I did not know
19 that there was data available for
20 Nucynta that told -- down to the
21 pharmacy level.

22 BY MR. JANUSH:

23 Q. And the same goes for
24 Duragesic?

1 A. Yes.

2 Q. Okay. Earlier we talked
3 about IntegriChain third-party data. Do
4 you remember that?

5 A. Yes.

6 Q. Okay. Would your answers be
7 the same, that you didn't know about a
8 company -- a third-party company called
9 ValueCentric 852 data or 867 data before
10 2017?

11 MR. BARKER: Object to form.

12 THE WITNESS: I did learn
13 about ValueTrak, ValueCentric
14 data. That they were the ones
15 supplying the blinded 852, 867
16 data.

17 BY MR. JANUSH:

18 Q. Okay. And is that the sole
19 capacity -- how did you learn about
20 ValueTrak or ValueCentric data?

21 A. I believe -- I don't recall
22 the exact date, but during our monthly
23 compliance reviews, it was presented as a
24 data source that could be used,

1 potentially, to help investigate
2 questionable orders.

3 Q. Okay. It was not a data
4 source that was built into your
5 suspicious order monitoring protocols to
6 stop a suspicious order in realtime,
7 right?

8 A. We have another order
9 monitoring program that reviews the
10 orders. Value -- it's a separate --
11 ValueTrak is a separate IT.

12 Q. So the answer to my question
13 is yes, right?

14 MR. BARKER: Object to form.

15 BY MR. JANUSH:

16 Q. My question was --

17 A. ValueTrak --

18 Q. It was not --

19 A. Sorry.

20 Q. My question was it was not a
21 data source that was built into your
22 suspicious order monitoring protocols to
23 stop an order in realtime, right?

24 MR. BARKER: Object to form.

1 THE WITNESS: Yes, it was
2 not our order monitoring program.

3 BY MR. JANUSH:

4 Q. Okay. And it wasn't a
5 component of your order monitoring
6 program, correct?

7 MR. BARKER: Object to form.

8 THE WITNESS: It was part of
9 our investigation process, that
10 our -- during the investigation,
11 did use that data.

12 BY MR. JANUSH:

13 Q. Okay.

14 (Document marked for
15 identification as Exhibit
16 Dempsey-4.)

17 BY MR. JANUSH:

18 Q. Let me show you what's been
19 marked as Exhibit 4. And this is a
20 parent cover e-mail, JAN-MS-00454956 with
21 an attachment. This runs sequentially
22 through 957 and 958. The attachment is
23 the third page, "High level overview of
24 JOM suspicious or excessive order

1 monitoring SOM."

2 Do you see that, third page?

3 A. I'm -- I'm reading that now.

4 Q. So I'm going to -- I'm
5 actually going to first turn your
6 attention -- I just wanted to run through
7 the header that you saw that the third
8 page existed so I gave you a complete
9 document.

10 Do you see that?

11 A. Yes.

12 Q. Okay. Turning to the first
13 page. This is from Luis Valcárcel to Ron
14 Kuntz and Paul Lowman.

15 Who is Luis or Luis
16 Valcárcel in the organization of
17 Ortho-McNeil?

18 MR. BARKER: Object to form.

19 THE WITNESS: Luis was in
20 trade.

21 BY MR. JANUSH:

22 Q. And do you remember what his
23 title was?

24 A. No, I'm sorry.

1 Q. And Ron Kuntz, who was he?

2 A. He was in marketing for
3 Nucynta.

4 Q. He was the director of the
5 pain franchise, right?

6 MR. BARKER: Object to form.

7 THE WITNESS: I don't recall
8 his actual title.

9 BY MR. JANUSH:

10 Q. And how about Paul Lowman?

11 A. I never -- I do not know who
12 he is.

13 Q. Okay. And this is
14 addressing the -- in -- underneath Luis's
15 e-mail, in the second paragraph,
16 "ValueTrak EDI 852 data has McKesson and
17 Cardinal constantly (sic) over 99 percent
18 in stock levels at a macro level. There
19 are some deviations from the 99 plus
20 stocking levels at a few selected
21 distribution centers."

22 Do you see that?

23 MR. BARKER: Object to form.

24 The witness had asked you before

1 for an opportunity to read the
2 document, Evan.

3 MR. JANUSH: Okay. I was
4 reading that sentence to her
5 though. I'm asking if she sees
6 what I've read.

7 THE WITNESS: I can see -- I
8 see what you've read.

9 BY MR. JANUSH:

10 Q. Did I read that question
11 correctly, or that statement correctly?

12 A. You did read the statement
13 correctly.

14 Q. Okay. And then the next
15 ensuing statement is, "ValueTrak EDI 852
16 data for ABC at a macro level is slightly
17 below 98 percent. There is further
18 analysis being conducted as there were
19 some distribution centers that were out
20 of stock on some dosage strengths."

21 Do you see that?

22 A. Yes, I do.

23 Q. So this seems to show that
24 trade was using this ValueTrak 852 data

1 to check stock of dosage strengths at
2 AmerisourceBergen distribution centers.
3 Would you agree with that?

4 MR. BARKER: Object to form.

5 THE WITNESS: Your
6 interpretation does seem to
7 support that they were monitoring
8 the inventory level at ABC.

9 BY MR. JANUSH:

10 Q. And, in fact, the -- the
11 following bullet statement seems to
12 confirm that, doesn't it, stating, "Luis
13 will join weekly calls with
14 AmerisourceBergen buyer, ABC buyer, and
15 JOM planner with an action plan to
16 proactively track stocking levels at the
17 distribution centers based on hot spot
18 markets and formulary wins. ABC agreed
19 to move inventory internally as needed."

20 Did I read that right?

21 MR. BARKER: Object to form.

22 THE WITNESS: Yes, you read
23 it correctly.

24 BY MR. JANUSH:

1 Q. What are hot spot markets?

2 A. I do not know.

3 MR. BARKER: Object to the
4 form.

5 BY MR. JANUSH:

6 Q. You are the director of
7 controlled substance compliance for
8 Janssen and you don't know what hot spot
9 markets are?

10 MR. BARKER: Object to form.

11 THE WITNESS: I do not know
12 what the intent was in this e-mail
13 from trade, what he meant by hot
14 spot markets.

15 BY MR. JANUSH:

16 Q. Okay. But it is addressing
17 proactively tracking stocking levels at
18 the distribution centers based on hot
19 spot markets and formulary wins, isn't
20 it?

21 MR. BARKER: Object to form.

22 THE WITNESS: That is what
23 it reads.

24 BY MR. JANUSH:

1 Q. What are formulary wins?

2 MR. BARKER: Object to form.

3 THE WITNESS: I don't know.

4 MR. BARKER: You need to
5 slow down.

6 BY MR. JANUSH:

7 Q. Let's turn to the next page.

8 "If there is going to be a
9 spike in demand in an identified
10 geographic area, trade needs to be made
11 aware. This can help in any potential
12 delays at the distributor and JOM level
13 due to suspicious order monitoring."

14 Do you see that?

15 A. Yes, I do.

16 Q. Have you -- do you have an
17 understanding as to why trade would need
18 to be aware if there is going to be a
19 spike in demand in an identified
20 geographic area?

21 MR. BARKER: Object to form.

22 THE WITNESS: If it is to a
23 distribution center that has never
24 received a product or is covering

1 area where there is an increased
2 medical need for our -- for the
3 medicine, if we know in advance,
4 we can get information from the
5 customer. And when we do -- when
6 it comes up as a questionable
7 order in our program, we'd have
8 all of the documentation in
9 advance. And we'd understand that
10 the questionable order is not
11 questionable, that there is a
12 justification, that there is
13 substantiated evidence to support
14 the demand.

15 BY MR. JANUSH:

16 Q. And this e-mail, with the
17 attachment is dated June 25th, 2012; is
18 that right, going to the cover page?

19 A. That is what the cover page
20 says.

21 Q. That's about, what, three
22 months after you joined as the director
23 of controlled substance compliance for
24 Janssen or JOM?

1 A. Yes.

2 Q. So at the last paragraph of
3 this second page ending in Bates number
4 957, the definition of suspicious and
5 excessive order is provided, is it not?

6 MR. BARKER: Object to form.

7 THE WITNESS: That is a
8 definition that the writer of the
9 e-mail had provided, is their
10 interpretation of what a
11 suspicious and excessive order is.

12 BY MR. JANUSH:

13 Q. Why don't you read that into
14 the record.

15 A. It states, "A potentially
16 suspicious or excessive controlled
17 substance order can be defined as an
18 order that exceeds the minimum order
19 quantity requirements and is above three
20 times (300 percent) the calculated
21 12-month per weekly order average. This
22 definition also applies to products that
23 are scheduled in one or more states but
24 not by DEA."

1 Q. Do you disagree that in June
2 of 2012 this was your company's
3 definition of a suspicious -- potentially
4 suspicious order?

5 A. That is the order monitoring
6 program's parameters that it was looking
7 for, so yes that was.

8 Q. So you don't disagree with
9 this statement, correct?

10 A. I do not disagree with the
11 statement that that is what the order
12 monitoring program was looking for.

13 Q. Okay. And by that we're
14 talking about three times or 300 percent
15 of the calculated 12-month per weekly
16 order average, right?

17 A. Yes.

18 Q. Now, turning to the last
19 page. That same definition carries over
20 onto the high level overview of JOM
21 suspicious or excessive order monitoring;
22 is that right?

23 MR. BARKER: Object to form.

24 BY MR. JANUSH:

1 Q. I'm highlighting it on the
2 screen for you --

3 A. Right. That is what our
4 order monitoring report or program does.

5 Q. Okay. Now moving to the JOM
6 suspicious order report. The first
7 bullet says, "BW report is generally
8 completed by 4:00 p.m."

9 What is the acronym BW stand
10 for?

11 A. So it's an SAP terminology,
12 which is an IT system called Business
13 Warehouse. We developed a report that
14 takes the last 12-month weekly order
15 average and factors in the three times
16 percent. So when you're -- when you
17 review the definition above, that's
18 exactly what this BW report does, is all
19 the orders go through it, and history is
20 compared and is -- that one single order
21 is compared to this threshold.

22 Q. When that one single order
23 is compared to threshold, how is that
24 order compared -- how is it broken down

1 in terms of at a SKU or SKU level of a
2 product?

3 A. It is per customer, per DEA
4 license SKU.

5 Q. So just so we're on the same
6 page, and I'm going to break that down
7 into layman's terms, or try to since I'm
8 not in your business, when that BW report
9 is run or generally completed at
10 4:00 p.m., and it's comparing a
11 particular customer's order against their
12 rolling 12-month per weekly order
13 average, it's comparing for particular
14 SKUs for particular drug types and drug
15 strengths against the same drug type and
16 drug strength in the new order; is that
17 right?

18 A. Yeah, it takes the SKU,
19 which is that dosage formulation, and it
20 compares to the past 12-month rolling
21 average.

22 Q. Okay. So we are on the same
23 page then. What it doesn't do,
24 therefore, and correct me if I'm wrong,

1 is address if hypothetically a wholesaler
2 like a Cardinal, AmerisourceBergen, or
3 McKesson, had previously purchased
4 Duragesic at 50-milligram strength, but
5 in an ensuing order, present day, so to
6 speak, purchased at a 75-milligram
7 strength, your system wouldn't compare
8 the 75-milligram order being made in the
9 present tense to the 50-milligram orders
10 that had previously been made because
11 they are different SKUs or S-K-U-s; is
12 that right.

13 MS. BOODY: Object to form.

14 THE WITNESS: Yes.

15 BY MR. JANUSH:

16 Q. I didn't hear you. I'm
17 sorry. Is that right?

18 A. Yes.

19 Q. And moving beyond a
20 different SKU issue, for example, a
21 strength issue with Duragesic, that might
22 be produced in multiple different
23 strengths, your order monitoring system
24 or suspicious order monitoring system

1 also wouldn't have captured the aggregate
2 of opioid products sold to a wholesaler
3 customer and compared the aggregate order
4 history against the present day order;
5 isn't that also true?

6 MR. BARKER: Object to form.

7 BY MR. JANUSH:

8 Q. For example, to make this
9 more clear, we'll just speak in terms of
10 Nucynta and Duragesic. Okay?

11 A. Okay.

12 Q. So if hypothetically
13 Cardinal purchased Duragesic
14 50-milligram, 2 cases of 24 patches last
15 month with one case of Nucynta ER -- and
16 this is obviously a hypothetical, because
17 Nucynta, I appreciate, was sold in 2016
18 or thereabouts. Your system in a
19 hypothetical universe of 2012 wouldn't
20 have compared a new order by Cardinal,
21 where Duragesic was being purchased at
22 75 milligrams and Nucynta IR was being
23 purchased instead of Nucynta ER.
24 Those -- the past order and the current

1 order, having completely different SKUs,
2 would not have been compared against each
3 other under your suspicious order
4 monitoring system; isn't that right?

5 MR. BARKER: Object to form.

6 MS. BOODY: Object to form.

7 THE WITNESS: Every order
8 that we received with a customer
9 based on the SKU is reviewed for
10 historical ordering of that SKU.
11 We do also take in context total
12 products that are shipped to
13 Cardinal and McKesson, and we
14 compare total products to
15 controlled substances. We're
16 monitoring how much of controlled
17 substances they're ordering
18 compared to other of our J&J
19 products.

20 So quarterly basis we're
21 reviewing that information. So --
22 so we have more visibility to what
23 volume of controlled substances
24 are they ordering compared to

1 other J&J products.

2 BY MR. JANUSH:

3 Q. Thank you for your
4 clarification. I was speaking to
5 realtime monitoring. And you just added
6 some answers that concerned quarterly
7 reviews, how you would use, as an
8 example, percent of controlled substances
9 against the percent of uncontrolled
10 substances as a metric to review sales to
11 a wholesaler, right?

12 MR. BARKER: Object to form.

13 THE WITNESS: We used that
14 to track if there's any trends of
15 controlled substances going up
16 compared with the total volume
17 going to the wholesaler.

18 BY MR. JANUSH:

19 Q. Okay. And that's a
20 quarterly review, right?

21 A. It's done on a quarterly
22 basis.

23 Q. Okay. To answer my earlier
24 question, in realtime your system

1 wouldn't have picked up or compared a
2 Duragesic 50-milligram case order against
3 a new order by the same purchaser of
4 Duragesic 75 milligrams; is that right?

5 MR. BARKER: Object to form.

6 THE WITNESS: The order
7 monitoring takes the order, the
8 SKU that they are requesting, and
9 compares the historical ordering
10 patterns of that SKU.

11 BY MR. JANUSH:

12 Q. Of that SKU. And of that
13 SKU means of that dosing, right?

14 A. Yes. That SKU is based on
15 the dosage.

16 Q. Now, here we are in 2012.
17 And it shows, in your bullet that I'm
18 highlighting, "Once the reason for the
19 increase is received, then the customer
20 service will run a ValueTrak report that
21 will show the customer's inventory and
22 compare to the demand of the increase."

23 Do you see that?

24 A. Yes, I do.

1 Q. So earlier when I spoke
2 about knowing that you had outside data
3 vendors providing reports concerning
4 wholesalers' purchases of product, you
5 advised that you didn't know about that
6 until 2017.

7 This shows that outside
8 vendors were being utilized by customer
9 service in 2012; isn't that the case?

10 A. What I had said is I did not
11 know that we had unblinded data to the
12 pharmacy level, that we did use ValueTrak
13 to understand the inventory levels at our
14 customers, the wholesaler.

15 (Document marked for
16 identification as Exhibit
17 Dempsey-5.)

18 BY MR. JANUSH:

19 Q. I'm going to hand you what
20 I've marked -- that's the wrong one.
21 Let's see -- as Exhibit 5. And this is
22 Bates number JAN-MS-03054480.

23 And it's an e-mail from Mike
24 Bulone to a host of folks at Johnson &

1 Johnson companies.

2 Do you see that at the top?

3 A. Yes.

4 Q. And it's dated March 17,
5 2013. And it's addressing the CSOS
6 overview B.PowerPoint regarding the
7 attachment.

8 A. Yes.

9 Q. Do you recall a point in
10 time where J -- Johnson & Johnson was
11 moving from a manual 222 DEA order form
12 to an electronic-based order form?

13 A. Yes, I do remember that we
14 moved from a paper based for the three
15 big wholesalers.

16 Q. Okay. Was it only for the
17 three big wholesalers that you moved from
18 paper-based forms to the electronic
19 forms?

20 A. Yes.

21 Q. So through the present day,
22 does Janssen use 222 forms for every
23 customer other than the three big
24 wholesalers?

1 A. Yes, we still use Paper 222.

2 Q. And when we speak about the
3 three big wholesalers, we're referring to
4 Cardinal, McKesson, and
5 AmerisourceBergen; is that right?

6 A. Yes.

7 Q. Okay. What caused you to
8 still use 222s with all other wholesalers
9 that you sell to?

10 A. They didn't request for
11 electronic.

12 Q. So Cardinal,
13 AmerisourceBergen, and McKesson all
14 requested an electronic system?

15 A. Yes.

16 Q. And what was the purpose
17 of -- of those requests to the extent
18 that you know?

19 A. From what I was aware, that
20 CSOS would be a streamlined process to --
21 for controlled substance Schedule II
22 ordering.

23 Q. What does CSOS stand for,
24 C-S-O-S?

1 A. Controlled substance
2 ordering system. I don't remember the
3 exact words.

4 Q. I thought so as well. I
5 just wanted to ask to clarify.

6 And I'd like to turn to the
7 attachment. And the attachment -- let me
8 lift this up a bit, at page -- it's
9 actually Page Zero of the slide. It's
10 the first page. And it states, "JOM" --
11 and I apologize I didn't give you the
12 Bates number for. The Bates number for
13 the attachment is JAN-MS-03115790.

14 And the attachment states at
15 the top, "JOM is the Pharma customer
16 service and distribution center for North
17 America with around 14 billion worth of
18 sales shipped every year."

19 Did I read that right?

20 A. Yes, you did read it right.

21 Q. And in the second bullet,
22 why don't you read the second bullet.

23 A. "Last year JOM shipped
24 1.6 billion worth of Class II narcotic

1 drug" -- "shipments."

2 Q. Keep going.

3 A. "Class II are drugs with
4 high potential for abuse with severe
5 psychological or physical dependency,
6 codeine, opium, et cetera. In order to
7 comply with DEA regulations for Class II
8 shipments, the JOM team manually entered
9 22,000 line items on paper-based DEA 222
10 forms."

11 Q. Do you agree with the
12 statement you just read?

13 MR. BARKER: Object to form.

14 THE WITNESS: I would offer
15 one clarifying point, that our
16 ADHD medicines which is a
17 psychotropic, he is throwing that
18 in here as well as Class II.

19 BY MR. JANUSH:

20 Q. And with that caveat, do you
21 agree with all of the -- the language
22 included in Bullet 2 here?

23 MR. BARKER: Object to form.

24 THE WITNESS: I do. If you

1 include the psychotropics, I agree
2 with what is written here, that
3 this was Greg -- Mike -- what's --
4 what's being said in regards to
5 how many line items in 222
6 customer service was handling.

7 BY MR. JANUSH:

8 Q. Okay. Do you agree with
9 the -- what you also read, that Class II
10 drugs are drugs with high potential for
11 abuse with severe psychological or
12 physical dependencies, (codeine, opium,
13 et cetera)."

14 Do you agree with that?

15 MR. BARKER: Object. Object
16 to form.

17 THE WITNESS: I -- I
18 agree -- I do not -- I agree with
19 what he wrote in regards to that
20 we handle Schedule II
21 psychotropics and narcotics, and
22 they are controlled substances
23 based on their high potential for
24 abuse. That is why FDA and DEA

1 has made them Schedule II
2 products.

3 BY MR. JANUSH:

4 Q. Ma'am, I just asked if you
5 agreed that Class II are drugs with high
6 potential for abuse with severe
7 psychological or physical dependencies.
8 Do you agree with that?

9 MR. BARKER: Object to form.

10 THE WITNESS: Class --

11 Schedule II drugs are scheduled
12 based on their high potential for
13 abuse, yes.

14 I don't know where he got
15 the severe psychological and
16 physical dependencies.

17 BY MR. JANUSH:

18 Q. Do you disagree with that
19 language?

20 MR. BARKER: Object to form.

21 THE WITNESS: I would have
22 worded it as drugs with high
23 potential for abuse or misuse.

24 So -- that -- that is why they are

1 Schedule II.

2 THE VIDEOGRAPHER: Counsel,
3 you might have pulled down your
4 microphone.

5 BY MR. JANUSH:

6 Q. I want you to turn to Page 4
7 of the slideshow, and address JOM
8 estimated business benefits. This
9 appears to be the cost benefits of
10 switching to an electronic system from
11 the Form 222 system; is that right?

12 MR. BARKER: Object to form.

13 BY MR. JANUSH:

14 Q. You can review the whole
15 document if you need to, to answer that,
16 but --

17 A. I'd like to.

18 This appears to be the
19 line -- the processes that are involved
20 in receiving, reviewing the Paper 222s,
21 and the cost benefit if you go to
22 electronic form.

23 Q. All right. Great. So let's
24 skip down to, and I'll circle it in blue

1 ink for you, DEA compliance notification.
2 Current baseline quarterly. Future
3 performance going to the electronic
4 system every 48 hours.

5 Do I have that right?

6 A. Yes, you do.

7 Q. Okay. So what was the DEA
8 compliance notification that you were
9 then currently making quarterly?

10 A. Every quarter we need to
11 provide ARCOS reports. So what we're
12 saying is DEA only quarterly saw our
13 transactional data because we uploaded
14 our ARCOS data on a quarterly basis.
15 With CSOS, DEA has direct visibility.
16 Every 48 hours, they get realtime
17 transaction information from JOM.

18 Q. Okay. But they are only
19 able to get that for the big three,
20 AmerisourceBergen, Cardinal, McKesson; is
21 that right?

22 A. The CSOS scope was only for
23 the big three. The large -- the larger
24 transactions.

1 Q. Incidentally, I missed that
2 within this entire CSOS background. Can
3 you show me or point out where this was
4 limited to only the big three? All I see
5 are words like wholesalers generally.

6 A. All right. So this was the
7 kickoff for the project.

8 Q. Yep.

9 A. We also followed the project
10 in our monthly compliance meetings for
11 suspicious order monitoring.

12 Q. So in the kickoff, there's
13 no mention -- is there a mention that
14 this only concerned the big three?

15 MR. BARKER: Object to form.

16 THE WITNESS: I don't recall
17 if that was the intent. I knew
18 the intent which prioritized
19 the -- the large wholesalers.

20 BY MR. JANUSH:

21 Q. And to be clear, when I --
22 when I had this Page Zero, the cover page
23 out, and it was addressing last year JOM
24 shipped 1.6 worth of Class II narcotic

1 shipments, JOM is not Noramco, correct?

2 A. Yes. They are not Noramco.

3 Q. JOM is Johnson Ortho-McNeil,
4 correct?

5 A. Yes.

6 Q. And JOM, the bullet above
7 it, is the Pharma customer service and
8 distribution center for North America
9 with around 14 billion worth of sales
10 shipped every year.

11 This is referring to Johnson
12 & Johnson's pharmaceutical sales that are
13 shipped through JOM; is that right?

14 MR. BARKER: Object to form.

15 THE WITNESS: I don't know
16 if that was the intent of that
17 bullet or where this data came
18 from. But it speaks to, I do know
19 that our two distribution centers
20 under JOM do handle the
21 pharmaceutical products of
22 Janssen.

23 BY MR. JANUSH:

24 Q. Okay. I'm just trying to

1 delineate very clearly between when we're
2 speaking about JOM and when we're
3 speaking about Noramco. Do you
4 understand that goal?

5 A. Yes.

6 Q. Okay. And in this document,
7 you are -- not you, JOM is addressing
8 what JOM business is, right?

9 A. Yes. And as I mentioned
10 before, they lumped in Schedule II, the
11 psychotropic ADHD meds as well, instead
12 of just narcotics.

13 Q. Okay.

14 (Document marked for
15 identification as Exhibit
16 Dempsey-6.)

17 BY MR. JANUSH:

18 Q. I'm going to move to what
19 I've marked as Dempsey Exhibit 6. This
20 is an e-mail string with an attachment.
21 This concerns communications between you
22 and Ron Kuntz that was then forwarded on
23 by Ron to Patricia Yap. And I'm going to
24 read -- start by reading -- having you

1 read your e-mail in the middle of the
2 first page where you wrote to Ron, "I
3 just called my friend."

4 Why don't you start there?

5 A. "I just called my friend
6 that retired in December from Purdue,
7 ex-DEA, that managed the relationship
8 with DEA during the OxyContin years, and
9 setup their suspicious order monitoring
10 program. He was the one who went to
11 visit pharmacies with wholesalers. I
12 attached benchmarking notes taken when
13 JOM chatted with the Purdue on the
14 suspicious order monitoring program last
15 year."

16 Q. Now, let's just stop and
17 pause right there.

18 "I attached benchmarking
19 notes taken when JOM chatted with Purdue
20 on the SOM program last year."

21 Do you see that?

22 A. Yes.

23 Q. And that's not saying, "I
24 attached benchmarking notes when Noramco

1 chatted with Purdue on the SOM program
2 last year"; is that right?

3 A. Right. It was JOM.

4 Q. Okay. And again, as you
5 just testified moments ago, JOM is
6 different from Noramco, right?

7 A. Yes.

8 Q. Okay. And reading below his
9 business card that's embedded in your
10 e-mail -- why don't you read below?

11 A. "He met with sales force
12 with Purdue. He also was the one that
13 called DEA when sales force found
14 suspicious doctors. Law department gave
15 suspicious order monitoring training to
16 sales."

17 Continue?

18 "I am not sure of the
19 project scope. Didn't give him any
20 details but said you may call him.
21 Please do. You will enjoy it. He was
22 widely respected in the New Jersey pharma
23 industry group."

24 Q. Now, before I go any

1 further, do you remember proposing to Ron
2 Kuntz that Jack Crowley come in after he
3 retired from Purdue to pitch or address
4 the potential for a sales training
5 seminar for the sales folks to spot high
6 prescribers that might be suspicious?

7 A. Can you repeat your
8 question?

9 Q. Sure. Jack Crowley was your
10 counterpart at Purdue, correct, in terms
11 of a suspicious order monitoring
12 compliance role that he played, right?

13 MR. BARKER: Object to form.

14 THE WITNESS: He was the
15 manager of controlled substance
16 compliance. He was a leader
17 there.

18 MR. BARKER: You need to
19 slow down.

20 BY MR. JANUSH:

21 Q. Was he -- was he your
22 counterpart, your peer at Purdue?

23 A. As far as I'm aware, yes.

24 Q. And he is an ex-DEA

1 employee, correct?

2 A. Yes. He retired from DEA.

3 Q. And he ultimately, in or
4 around 2000 -- or in between 2012, March
5 of 2012 and this e-mail in June of 2013,
6 he -- well, actually it says it. In
7 December of 2012, he retired from Purdue.

8 Do you recall that?

9 A. Yes.

10 Q. And he created a consulting
11 business. Do you remember that?

12 A. Yes.

13 Q. And he advised you of his
14 ability to come into Janssen and create a
15 sales training seminar to teach sales
16 force, as he did at Purdue, how to spot
17 questionable prescribers of interest.

18 Do you remember that?

19 MR. BARKER: Object to form.

20 THE WITNESS: I remember
21 that Ron asked -- he was
22 evaluating that -- our suspicious
23 order monitoring program. And I
24 suggested that he talk to Jack. I

1 wasn't involved in the meetings
2 or -- so I just forwarded his
3 information.

4 So what the content, I
5 was -- I was not really involved
6 with those meetings with Ron.

7 So he asked for who can give
8 him advice on understanding
9 what -- what is typical. And I
10 provided a source for him.

11 BY MR. JANUSH:

12 Q. I don't understand your
13 answer. What is typical for what?

14 A. So as we were preparing for
15 Nucynta, I was asked, did I know anybody
16 in industry that could provide
17 information on what's done with the sales
18 force in regards to training.

19 Q. Okay. And you provided Jack
20 Crowley --

21 A. Yes.

22 Q. -- as a reference?

23 A. Right.

24 Q. Okay. And what follows in

1 this same string from June of 2013 on the
2 very next page is your earlier e-mail to
3 Michael Levitt of March 21, 2012.

4 Do you see that?

5 A. Yes, I do.

6 Q. And this is concerning that
7 you scanned your nine pages of notes.
8 "Up to you to complete a summary and
9 share with JOM. Nice job. Don't you
10 think?"

11 You wrote that, right?

12 MR. BARKER: I think you
13 misread that.

14 BY MR. JANUSH:

15 Q. "I scanned my nine pages of
16 notes... up to you to compile" -- my
17 apologies --

18 A. Compile.

19 Q. -- not complete -- "compile
20 a summary and share with JOM... nice
21 job, don't you think?"

22 Did I read that accurately?

23 A. You did read that
24 accurately.

1 Q. Okay. And who is Michael
2 Levitt?

3 A. He was the DEA compliance
4 manager for JOM.

5 Q. Was he under you?

6 A. Yes.

7 Q. So you were the DEA -- you
8 were the -- excuse me -- the director of
9 controlled substance compliance, and
10 Michael Levitt was your -- a direct
11 report of yours who managed DEA
12 compliance?

13 A. Yes.

14 Q. Okay. And following below
15 that is March 21, 2012, e-mail from Jack
16 Crowley, while he was at Purdue, to you
17 and Michael Levitt addressing the
18 pre-meeting that was had on March 20th;
19 is that right?

20 A. Yes, this is the
21 pre-meeting, what he wanted to cover at
22 the meeting.

23 Q. Okay. And going to the
24 bottom of the page, or the middle of the

1 page, he's addressing some background
2 information that, "Purdue enhanced its
3 order monitoring program beginning in
4 early 2008."

5 Do you see that?

6 A. Yes, I do.

7 Q. And then he addressed formal
8 monitoring meetings that were held with
9 various wholesalers; is that right?

10 A. The authorized distributors,
11 yes.

12 Q. Okay. And we'll skip
13 forward to the attachment, which is
14 Bates-stamped JAN-MS-03115790.

15 These are the nine pages of
16 notes that you addressed with Michael
17 Levitt that you attached to the e-mail,
18 aren't they?

19 MR. BARKER: Object to form.
20 You've got a gap in your Bates
21 numbers in this document.

22 MR. JANUSH: Yes, I do.

23 It's due to the whole production
24 fight that we fought over. You

1 may recall how these were
2 produced -- originally withheld as
3 nonresponsive, and then produced.
4 There was a reason for pushing
5 back this deposition.

6 So unfortunately --

7 MR. BARKER: This is one of
8 them?

9 MR. JANUSH: This is one of
10 those documents that Seth Baglin
11 said could not reproduce it in the
12 correct Bates range. I would have
13 liked it to have been done right
14 as well.

15 BY MR. JANUSH:

16 Q. Going back to my question.
17 These are your nine pages of notes from
18 my --

19 A. This looks like my
20 handwriting and my notes, yes.

21 Q. Okay. And from a -- from a
22 3/20/12 pre-meeting, at the top. Those
23 are your notes from the pre-meeting; is
24 that right? Right?

1 And then moving to the
2 bottom, 3/21/12, that's the more complete
3 in-person meeting; is that right?

4 A. Yes.

5 Q. And this concerns what is
6 stated in the earlier e-mail when you
7 wrote to Ron Kuntz about your notes from
8 when JOM benchmarked with Purdue, right?

9 A. These are the notes that I
10 took when we benchmarked with Purdue on
11 their suspicious order monitoring
12 program, and it was attached to the
13 e-mail that I sent to Ron Kuntz.

14 MR. JANUSH: Not answering
15 my question specifically. So I'm
16 going to move to strike as
17 nonresponsive. I'm focusing on
18 JOM.

19 BY MR. JANUSH:

20 Q. My question was, this
21 concerns what is stated in the earlier
22 e-mail when you wrote to Ron Kuntz that
23 you were attaching notes from when JOM
24 benchmarked with Purdue, right? Just

1 asking for a yes or no here.

2 A. Yes, these are the notes in
3 reference, yes.

4 Q. Not from when Noramco
5 benchmarked with Purdue. From when JOM
6 benchmarked with Purdue, right?

7 A. Yes, JOM.

8 Q. Okay. We're going to go
9 through some of these notes. All right?

10 A. Mm-hmm.

11 Q. And really, what my goal
12 here is to just figure out what -- what
13 information was conveyed by Mr. Crowley
14 and Purdue and perhaps other attendees to
15 JOM and you and your colleagues during
16 this meeting.

17 So first, in the pre-meeting
18 on March 20th, 2012, Mr. Crowley or
19 someone, appears to have stated, "Purdue
20 has a contract with wholesalers to buy
21 sales data."

22 Do you see that?

23 A. Yes, I do.

24 Q. Did you inquire as to what

1 that actually means in practice, who the
2 contract is with with wholesalers to buy
3 sales data?

4 A. No.

5 Q. Do you know if Purdue had a
6 contract with Cardinal,
7 AmerisourceBergen, and McKesson to buy
8 sales data?

9 A. No.

10 Q. Never inquired?

11 A. No.

12 Q. And next statement is,
13 "Design a system so that they get
14 realtime information about wholesaler
15 sales."

16 Do you see that?

17 A. Yes.

18 Q. Did you -- was this just
19 informational as setup for the next day,
20 or did you get into a discussion
21 regarding how Purdue designed a system so
22 that they could get realtime information
23 about wholesaler sales?

24 A. This was just a high level

1 discussion point of elements that we were
2 going to discuss at the benchmark
3 meeting.

4 Q. Got it. So let's just then
5 move forward to the benchmark meeting if
6 these elements are covered therein.

7 We'll go to the bottom of
8 the page, 3/21/2012. Stephen Seid
9 executive director, national accounts,
10 Purdue, was present; is that right?

11 A. Yes.

12 Q. Jack Crowley, Controlled
13 Substances Act compliance, Purdue. And
14 Rebecca Lyons listed as a VP of JOM.
15 What was Rebecca Lyons' role?

16 A. She had accountability for
17 the two distribution centers. I forget
18 exactly what her title was. But the
19 operations reported in to her.

20 Q. Okay. Mike Levitt, he is
21 who we discussed earlier that was a DEA
22 compliance manager?

23 A. Yes.

24 Q. How about Bruce Keale?

1 A. Finance on the leadership
2 team at JOM.

3 Q. Why would finance have been
4 involved in this benchmarking meeting?

5 A. I wanted all the leaders to
6 understand the requirements of suspicious
7 order monitoring.

8 Q. Okay. How about Greg
9 Wolski?

10 A. He was at the time, 2012,
11 customer service.

12 Q. All right. And so, would it
13 have been -- let's move to the next page
14 ending in Bates number 03115791. And it
15 says, "Purdue enhanced in 2008, designed
16 program to characterize data exposure to
17 retail data, 'know your customers'
18 customer."

19 Do you see that?

20 A. Yes, I do.

21 Q. So here you were in 2012, in
22 March, specifically March 21, 2012,
23 benchmarking with Purdue, right?

24 A. Yes.

1 Q. And you were learning that
2 Purdue, in 2008, designed their
3 suspicious order monitoring program to
4 characterize data exposure to retail data
5 to know your customers' customer. Is
6 that also right?

7 MR. BARKER: Object to form.

8 THE WITNESS: That is --
9 that is what Purdue relayed to us.

10 BY MR. JANUSH:

11 Q. Janssen didn't follow
12 Purdue's benchmark, did they?

13 MR. BARKER: Object to form.

14 BY MR. JANUSH:

15 Q. You can answer.

16 A. We -- we -- our system
17 provided the data that DEA had requested
18 from us. And we had no -- with our
19 multiple engagements with DEA in -- in
20 2013, we talked about this, you know, and
21 we were not -- the DEA did not expect
22 that information from us at that time,
23 for our Duragesic and Nucynta.

24 Q. That was a great answer to a

1 question I never asked so I'm going to
2 move to strike as nonresponsive.

3 Do you remember my actual
4 question?

5 MR. BARKER: Object to form.

6 THE WITNESS: Yes. You
7 asked if JOM implemented a know
8 your customers' customer --

9 BY MR. JANUSH:

10 Q. No, that's not what I asked.
11 I said Janssen didn't follow Purdue's
12 benchmark, did they?

13 MR. BARKER: Object to form.

14 THE WITNESS: We --
15 actually, this entire benchmark we
16 did incorporate some of the
17 recommendations --

18 BY MR. JANUSH:

19 Q. We'll get there.

20 A. -- but the specific know
21 your customers' customer, we did not
22 include it as an enhancement to our
23 system at that time.

24 Q. Okay. Did you include know

1 your customers' customer in order to get
2 data exposure to retail data at any time
3 into your suspicious order monitoring
4 realtime system?

5 A. There were some cases where
6 we attempted to use our 867 data to see
7 where our Duragesic and Nucynta was
8 going. But because it was blinded, it
9 was a challenge.

10 But it was only when we --
11 we were always monitoring the landscape.
12 And if for example, we heard about
13 Lakeland, Florida, we did do some
14 analysis of the data as best we could to
15 determine how much we were shipping to
16 that region, to see if there was any
17 suspicious activity. So we did try to
18 use our 867 data, but it wasn't a routine
19 data that was reviewed constantly. It
20 was used when we needed to investigate a
21 questionable order or if -- if we heard
22 through the news that there was a region
23 that was in question.

24 Q. Stated differently. Janssen

1 and JOM didn't incorporate retail level
2 data points into its realtime suspicious
3 order monitoring protocol, correct?

4 MR. BARKER: Object to form.

5 THE WITNESS: No. We did --
6 we had an order monitoring
7 algorithm that did not include
8 retail data.

9 BY MR. JANUSH:

10 Q. And moving down to the
11 middle of the page. It says, "Need
12 relationship with DEA. Send message to
13 DEA so they know what you're doing and
14 they will leave you alone."

15 Do you see that?

16 A. Yes, I do.

17 Q. Now, I'm going to move on to
18 the following page. And here Jack
19 Crowley is advising that the SOP at
20 Purdue had to be strengthened. Am I
21 right?

22 A. That is the note that I
23 took.

24 Q. And he addressed what SOM

1 committee looked like, with a
2 chairperson, VP general counsel, a VP
3 corporate secretary chief, an executive
4 director DEA, and Steve, as the national
5 accounts -- that's -- that's talking
6 about Stephen Seid, right, or Seid?

7 A. I don't know if it's --

8 Q. Who was involved in your
9 meeting with you?

10 We addressed his name at the
11 front page of attendees?

12 A. Stephen, okay.

13 Q. Is that right?

14 A. I would assume yes.

15 Q. Okay. A director of
16 suspicious order monitoring program,
17 security investigation.

18 What is this? I couldn't
19 read it. It says attorney and I couldn't
20 make out, is that an "on" or "or
21 prescriber"?

22 A. I don't recall what that is.

23 Q. It's your handwriting. I'm
24 just asking if you can make it out.

1 A. No. It looks like attorney
2 on prescriber.

3 Q. What would that mean?

4 MR. BARKER: Object to form.

5 THE WITNESS: I don't
6 recall.

7 BY MR. JANUSH:

8 Q. And then professional reps
9 from sales force and systems are the last
10 folks that were on this committee; is
11 that right?

12 A. Yes.

13 Q. Okay. And some of the
14 things that you were told during this
15 benchmark included meet monthly -- I'm
16 going to circle it. Discuss trends.
17 Focus on certain accounts or hot spot
18 areas.

19 Do you see that?

20 A. And in this, I know what
21 this -- I did not know what the trade
22 individual was talking about. But in
23 this case, that is diversion hot spot
24 areas.

1 Q. Isn't it also a hot spot
2 area an area that got a high prescribing
3 rate of opioids?

4 A. I don't know. At this time
5 it was those areas where there were
6 abuse, hot spots.

7 Q. And --

8 A. That was my -- my
9 interpretation from 2012.

10 Q. And -- and isn't hot spot
11 areas where there is a high amount of
12 abuse and diversion correlated to hot
13 spot areas where there's a high amount of
14 prescribing?

15 A. I don't know that data to --
16 to make an answer on that.

17 Q. And it says, "Look at all
18 products."

19 Do you see that?

20 A. Yes.

21 Q. "Have an agenda." Do you
22 see that?

23 A. Yes.

24 Q. At this time in March of

1 2012, you were being guided that Purdue
2 looks at all products when -- when it
3 revises its suspicious order monitoring
4 standard operating procedures, right?

5 MR. BARKER: Object to form.

6 THE WITNESS: That is what
7 they reviewed to us.

8 BY MR. JANUSH:

9 Q. And earlier you and I were
10 discussing the concept of Janssen or JOM
11 only looking and running its suspicious
12 order monitoring calculation against the
13 same SKU so that an order would come up
14 as suspicious when the same SKU was
15 compared against a prior order involving
16 that specific product and strength, i.e.,
17 SKU. Remember that discussion?

18 A. I do remember that
19 discussion.

20 Q. Okay. Purdue was doing it
21 differently, weren't they?

22 MR. BARKER: Object to form.

23 THE WITNESS: I don't recall
24 if what he was talking about was

1 all of Purdue's products, meaning
2 controlled and noncontrolled, or
3 if they meant at the drug class.

4 It was a high level
5 discussion. We didn't get into
6 the detail of what they actually
7 looked at in regards to all the
8 products.

9 BY MR. JANUSH:

10 Q. Okay. And it says, "Between
11 meetings meet with wholesalers, orders
12 looked at daily basis"; is that right?

13 A. That's what it says.

14 Q. "Channel strategy, 866 data,
15 orders monitored reach out. Order arrow,
16 use day-to-day ValueCentric data to send
17 message when doesn't meet guidelines."

18 What does that mean, "to use
19 day-to-day ValueCentric data to send
20 message when it doesn't meet guidelines"?

21 A. What that means is because
22 we had visibility to what the
23 wholesalers' inventory at their DC is
24 with this ValueCentric data, if a

1 questionable order comes in that doesn't
2 meet the typical ordering pattern or
3 volumes, we use this data to -- before we
4 reach out to the customer because their
5 order does not meet what they currently
6 have in inventory that -- that they --
7 the questionable order amount doesn't
8 appear to be needed. That's what that
9 means. And --

10 Q. It says, "Use day-to-day
11 ValueCentric data to send message when
12 doesn't meet guidelines."

13 Was -- was there a way to
14 send message within ValueCentric?

15 A. No. This was -- customer
16 service.

17 Q. He just meant to send -- he
18 just meant to send the message that
19 something is amiss?

20 A. Yes.

21 Q. What does it mean when you
22 wrote, "Different" -- when you took the
23 notes, "Different algorithm for SC-867
24 data"?

1 A. I don't recall.

2 Q. What is SC?

3 A. I don't remember.

4 Q. "Trend prescriber data."

5 You know what this means, don't you?

6 A. Yes, I do.

7 Q. What does it mean?

8 A. I am -- what he was saying
9 at a high level, that Purdue does use
10 prescriber data and analyze where it's
11 coming from.

12 Q. In other words, they were
13 looking at prescriber data as a potential
14 red flag, right?

15 MR. BARKER: Object to form.

16 THE WITNESS: It appears
17 that they were for their products.

18 BY MR. JANUSH:

19 Q. And Janssen and JOM were not
20 doing that, correct?

21 MR. BARKER: Object to form.

22 THE WITNESS: No, for our
23 Duragesic and Nucynta and other
24 scheduled products, we did not do

1 trend analysis on the prescriber
2 data as I previously said. We
3 stopped at the wholesaler.

4 BY MR. JANUSH:

5 Q. Did you know that your sales
6 group was doing trend analysis on its
7 higher prescribers of Nucynta and
8 Duragesic?

9 A. I did not know.

10 Q. Did you know that Janssen
11 was ranking its high Duragesic
12 prescribers and calling them Duragesic
13 loyalists in spreadsheets that were
14 shared with the sales force?

15 A. No, I did not know that.

16 Q. Did you know that Janssen,
17 while you were head of controlled -- you
18 still are, but while you were director of
19 controlled substance compliance, was in
20 2013 and perhaps earlier ranking doctors
21 based on whether they were platinum,
22 gold, silver, or bronze, based on how
23 many long-acting and short-acting Janssen
24 opioid products they were writing?

1 MR. BARKER: Object to form.

2 THE WITNESS: No.

3 BY MR. JANUSH:

4 Q. Is that information that you
5 would have wanted to know after meeting
6 with Jack Crowley and given -- been given
7 benchmarking guidance about looking at
8 prescriber data trends?

9 A. No. I was responsible for
10 ensuring our order monitoring process was
11 giving what DEA requested. And through
12 numerous engagements, every two to
13 three years we reviewed our program with
14 DEA. And they expected the wholesalers
15 to get that information. You know, we
16 asked for recommendations, and they never
17 told us that they needed that information
18 from us.

19 Q. Is it at all possible, have
20 you contemplated the fact that the DEA
21 might not have known what Janssen's
22 internal capabilities were in 2012 and
23 after?

24 MR. BARKER: Object to form.

1 THE WITNESS: I don't know
2 how to answer that.

3 BY MR. JANUSH:

4 Q. Let me ask it differently.
5 In meeting with the DEA, did you ever
6 say, "Hey, DEA, our sales folks are
7 tracking the highest, hottest prescribing
8 doctors in hot spot areas, and we target
9 them for sales. Do you want us to be
10 looking at those doctors to be analyzing
11 them as part of our suspicious order
12 monitoring program?"

13 Did you ever do that?

14 MR. BARKER: Object to form.

15 THE WITNESS: I only learned
16 from you right now that we had
17 that information. Therefore, no,
18 I would not have reported that to
19 DEA, because I did not -- I was
20 not aware of that information.

21 BY MR. JANUSH:

22 Q. But you're not the only
23 employee at JOM and Janssen that would
24 have had knowledge about how marketing

1 was done and how doctors were being
2 tracked for high prescribing status, were
3 you?

4 MR. BARKER: Object to form.

5 THE WITNESS: I am a
6 controlled substance compliance
7 leader.

8 BY MR. JANUSH:

9 Q. Right.

10 A. And I am -- I only get -- I
11 only see the processes that are required
12 from DEA.

13 Q. Let's go back to the first
14 page of the e-mail. This e-mail
15 concerning your notes about benchmarking
16 with Purdue and Jack Crowley, ex-DEA, and
17 addressing Purdue's SOM system that was
18 revised in '08 made it to Ron Kuntz,
19 product director of the pain franchise,
20 right?

21 A. I did forward it to him.

22 Q. And Ron forwarded notes with
23 an FYI to Patricia Yap or Trish Yap,
24 right?

1 MR. BARKER: Object to form.

2 THE WITNESS: Well, I am not
3 on this e-mail --

4 BY MR. JANUSH:

5 Q. But you see --

6 A. -- so I never received --

7 Q. You can see that now, right?

8 A. I can see that it was
9 forwarded.

10 Q. Sorry.

11 MR. BARKER: You need to let
12 her answer too.

13 MR. JANUSH: My apologies.

14 BY MR. JANUSH:

15 Q. And you know who Patricia
16 Yap is, right?

17 A. No, I do not.

18 Q. Did you know that Patricia
19 Yap was one of the most senior executives
20 in sales and marketing in the pain
21 franchise?

22 MR. BARKER: Object to form.

23 THE WITNESS: I just said I
24 didn't know who she was.

1 BY MR. JANUSH:

2 Q. We'll go to the bottom of
3 this page ending in 793 addressing zip
4 codes, "Prescribers of concern. Do
5 targeting zip code pharmacies. If had
6 CVS and Walgreens, would be benefit."

7 That's referring to if we
8 had CVS and Walgreens' data unblinded,
9 that would be a benefit; is that right?

10 A. At the time, the word
11 "unblinding" wasn't --

12 Q. No, I know, but I'm saying
13 the intent of what this is capturing.

14 A. The intent, yes.

15 Q. Right? I have this correct.

16 So it is, though,
17 addressing, "Zip codes, prescribers of
18 concerns. Do targeting zip code
19 pharmacies."

20 Do you see that?

21 A. Yep.

22 Q. And so Purdue was reviewing
23 prescribers of concern and targeting zip
24 code pharmacies, right?

1 A. That is what it says.

2 Q. Janssen and JOM were not,
3 correct?

4 A. Our program --

5 Q. You can give me the
6 monologue. But I'm asking if they were
7 not, yes or no.

8 A. We were not.

9 Q. Okay. Flipping to the next
10 page. "852 data, ordering pattern,
11 deviants in order data SKU. 867 data
12 suspicious, occasion limit wholesalers."

13 Did I read this correctly
14 what I'm boxing in?

15 A. Yes.

16 Q. So at this time in 2012,
17 Purdue is addressing that when they
18 redesigned their 2008 SOM system, this is
19 information that was included in the
20 standard operating procedures; is that
21 right?

22 A. I don't know if it was
23 included in their SOPs, but they said
24 this is what they consider in their

1 process.

2 Q. Got it.

3 A. I didn't review SOPs.

4 Q. Understood. Then below
5 there's a note, "Sensitive to
6 wholesalers' relationship. Purdue rarely
7 called and said concerned about account,
8 seen it before, will cut orders to
9 wholesalers."

10 Can you elaborate on that
11 part of the discussion?

12 A. Looking at it all these
13 years, I don't recall what the discussion
14 was about.

15 Q. Okay. Was Janssen and JOM
16 concerned about their wholesalers'
17 relationships as well --

18 MR. BARKER: Object to form.

19 BY MR. JANUSH:

20 Q. -- when it came to notifying
21 wholesalers about suspicious orders?

22 MR. BARKER: Object to form.

23 THE WITNESS: Our process,
24 we already engaged the wholesalers

1 whenever a questionable order was
2 discovered. So we had no concern.
3 We reached out, and if necessary
4 engaged trade to reach up to the
5 wholesaler leaders to make sure
6 that we had the justification and
7 documentation, or if there's -- if
8 an order was deemed suspicious.

9 BY MR. JANUSH:

10 Q. Moving to the next page
11 ending in 795. It states, "Uses SAP
12 algorithm whiz, tweaks algorithm
13 instantly." This refers to the fact that
14 the Purdue system, the computer algorithm
15 that runs the suspicious order monitoring
16 math could be tweaked instantly; is that
17 right?

18 MR. BARKER: Object to form.

19 THE WITNESS: We didn't get
20 into the details of their actual
21 algorithm. So I don't -- I wrote
22 what they said, that -- apparently
23 they said tweaks instantly.

24 BY MR. JANUSH:

1 Q. Okay. And you did get into
2 the system enough to see it, looking at
3 it on their screen, right? That's what
4 follows next; is that right?

5 A. No. I just took notes.
6 They said looking on the screen. They
7 didn't show us the screen.

8 Q. Got it.

9 A. So he said, "Looking at the
10 screen, you'd see" -- I apologize. I
11 didn't give that detail there.

12 Q. Okay. Go ahead.

13 A. They did not show -- it was
14 a phone call. There was nothing -- by
15 then there was no WebEx or sharing.

16 Q. Understood. So why don't
17 you read what he stated looking at their
18 screen, what they could see?

19 A. "Can see largest purchaser,
20 total sales." I don't know what W stands
21 for. Apologies. I don't remember. "How
22 many orders per day and strength info."

23 Q. Keep going.

24 A. "Compare three months, six,

1 nine, 12. Room for committee to make
2 comment categories, pending, complete,
3 refer with wholesaler to DEA."

4 Q. And now I'm just going to
5 skip forward to the page ending in 796.
6 And going to address, at the bottom, it
7 looks like information that was being
8 conveyed about what to look for.

9 But why don't you describe
10 what this is referring to. It says,
11 "Number of prescriptions per month,
12 number for your product in month for
13 certain strength, number paid by cash.
14 DEA can figure out by NDC and number who
15 made it. If 95 percent in cash is an
16 indicator."

17 What's that referring to?

18 A. I don't recall. I mean,
19 just looking at this, it looks like one
20 of the red flags about the cash.

21 Q. Okay. And then -- and then,
22 "Rebate reports, systems. See what's
23 distributed, paid by cash." How were
24 rebates reports and systems being used by

1 Purdue as a potential red flag alert?

2 MR. BARKER: Object to form.

3 THE WITNESS: I don't know

4 how they -- I don't -- I didn't

5 see SOPs. He just mentioned it as

6 I guess one of the elements that

7 they consider in their program.

8 BY MR. JANUSH:

9 Q. Okay. And in their program,
10 he's addressing at the bottom of Page
11 797, "Guidelines set up at ValueTrak
12 system. Tracks order variation versus
13 parameters. Agreements include order
14 variations. If new customer, holiday, or
15 year-end, there will be a variation.

16 Know" -- I can't see if that says, "how
17 look at it," or what that's referring to.

18 A. "Know we look at it."

19 Q. "Know we look at it. They
20 call Purdue so order is not held up."

21 So was the ValueTrak system,
22 as you understood it, embedded into
23 Purdue's suspicious order monitoring
24 system?

1 MR. BARKER: Object to form.

2 THE WITNESS: I don't know.

3 All I know is that they used the
4 data.

5 BY MR. JANUSH:

6 Q. Okay.

7 A. And how it was used, I do
8 not know.

9 Q. I think the answer's on the
10 top of the next page. And you might have
11 known it then, but maybe this will
12 refresh your recollection.

13 A. Thank you.

14 Q. You wrote, "ValueTrak, data
15 fed into their own system, more robust
16 than ValueTrak system. Use all inhouse
17 resources."

18 Did I read that right?

19 A. Yes. It looks like they
20 came up with their own program.

21 Q. But that they fed ValueTrak
22 data into their system. Do you see that?

23 A. Yes.

24 Q. Okay. JOM and Janssen did

1 not do that between your meeting,
2 benchmarking meeting on March 21, 2012,
3 and at least January of 2018; is that
4 right?

5 A. No, we did not.

6 Q. We'll move off this
7 document.

8 (Document marked for
9 identification as Exhibit
10 Dempsey-7.)

11 BY MR. JANUSH:

12 Q. I'm going to hand you what
13 I've marked as Exhibit 7.

14 And this is an e-mail from
15 you. Forgive the print. This is how it
16 came, in this horizontal small font.

17 And it's to John Daly
18 regarding mark DEA reports and meeting
19 minutes. And it's attaching multiple
20 attachments. I'm going to read them out.

21 Compliance security
22 considerations in 2013 PDF. How to
23 maintain an anti-diversion program in
24 PDF. State of the industry DEA

1 compliance in PDF. The core of
2 compliance reconciliation and
3 documentation in PDF.

4 And you wrote, after a
5 lead-in sentence or paragraph, "Here is
6 our opportunity at the DEA PDMA
7 conference" -- and let me stop right
8 there. PDMA refers to Buzzeo PDMA,
9 right?

10 A. Yes.

11 Q. And -- and that's that
12 division of IQVIA, right?

13 A. I believe it is now.

14 Q. Okay. And 13 would have
15 been a division of Cegedim, right?

16 MR. BARKER: Object to form.

17 THE WITNESS: I lost track.
18 I know it was Dendrite. It might
19 have been at that time.

20 BY MR. JANUSH:

21 Q. Yeah. So let me read it
22 again.

23 "Here is our opportunity at
24 the DEA PDMA conference. I heard a lot

1 of industry speak to DEA compliance.
2 They reviewed their practices. Check out
3 Slides 13/14... Industry practice...
4 Actavis/Watson."

5 Do you see that?

6 A. Yes.

7 Q. And then you attach the
8 PowerPoints that I was referring to
9 earlier.

10 These PowerPoints were at
11 least interesting enough to you
12 concerning anti-diversion and compliance
13 to forward them on to John Daly, correct?

14 A. Yes.

15 Q. Who is John Daly?

16 A. He was the general manager
17 at Noramco Wilmington location.

18 Q. Who what?

19 A. He was the general manager
20 at the Noramco Wilmington, Delaware,
21 location.

22 Q. Okay. I didn't hear
23 Wilmington. I apologize.

24 A. He was also my boss.

1 MR. JANUSH: Incidentally on
2 the record at this moment I'd like
3 to call for production of each of
4 these PowerPoints. They've been
5 withheld on grounds of
6 nonresponsiveness.

7 If they were important
8 enough for the witness to forward
9 on to her boss, they're responsive
10 enough for plaintiffs to get in
11 this litigation.

12 So we'd respectfully request
13 that Janssen take note of this.

14 MR. BARKER: I don't know
15 that they have not been produced.
16 But your -- your statement is --

17 MR. JANUSH: There may be
18 one of the four that have been,
19 but it's hard for me to
20 consolidate with the recent
21 reproduction that occurred.

22 But I know for a fact that
23 three of four have not been.

24 MR. BARKER: Your comment is

1 noted.

2 MR. JANUSH: Thank you so
3 much. I respect that.

4 BY MR. JANUSH:

5 Q. I'd like to focus, before I
6 move off this document, on one
7 particular -- couple particular comments.
8 I'm circling it.

9 With regard to the core of
10 compliance reconciliation and
11 documentation, there's a note underneath
12 that that says, "The infamous Teva deck.
13 Slide 6 is when she spoke to API
14 manufacturers. Your trash is other
15 people's treasure."

16 Do you remember that?

17 A. Yes.

18 Q. What did that mean, "Your
19 trash is other people's treasure"?

20 A. In regards to these slide
21 decks, and why I sent it to my boss, it
22 had nothing to do with suspicious order
23 monitoring. It was in response to
24 effective controls in the API

1 manufacturing building.

2 So it was reenforcing how
3 important it is to have access control,
4 make sure that there's two people at all
5 times, and preventing and making sure
6 that any liners or any packaging
7 equipment that could have come in contact
8 with API is properly disposed, because
9 your trash could be somebody's treasure
10 if there is residual API.

11 Q. And thank you for that
12 clarification.

13 And with respect to how to
14 maintain an anti-diversion program, you
15 wrote, "And finally a good overall deck
16 on DEA compliance. Key slides to review,
17 39 to 47 and 54."

18 That's your comment written
19 in this e-mail; is that right?

20 A. Yes.

21 Q. Okay. And do you know who
22 produced the -- the deck, how to maintain
23 an anti-diversion program, do you
24 remember that offhand?

1 A. Apologies, I don't recall.

2 Q. Okay. How about the next
3 one, state of the industry DEA
4 compliance? Do you remember who
5 presented that?

6 A. I'm guessing it was one of
7 the Buzzeeo consultants, but I don't know
8 who.

9 Q. Okay. Moving on to Slide 8.
10 I mean, excuse me. Exhibit 8.

11 (Document marked for
12 identification as Exhibit
13 Dempsey-8.)

14 BY MR. JANUSH:

15 Q. This is a document, an
16 e-mail, Bates number JAN-MS-02963560.

17 And this is from April 29,
18 2013, and it's addressing, I'll represent
19 to you by going to the very back page,
20 the second page, that "Nucynta and
21 Nucynta ER demand was slightly up last
22 week at the wholesaler. And one that
23 stuck out a bit more is Injured Workers
24 Pharmacy." It provides the address.

1 "They buy about 20,000 worth of Nucynta
2 and Nucynta ER per week. You may want to
3 research them. Our co-op can pull their
4 buying history if desired. Regards,
5 Greg."

6 Do you see that?

7 A. Yes, I do.

8 Q. And that's -- again, that's
9 Gregory Wolski, right?

10 A. Yes.

11 Q. And his role was what, can
12 you remind me?

13 MR. BARKER: Object to form.

14 THE WITNESS: At this time
15 he was head of planning channel
16 ops.

17 BY MR. JANUSH:

18 Q. Okay. And so he's
19 highlighting this Injured Workers
20 Pharmacy. Did you know whether that
21 Injured Workers Pharmacy is an
22 internet-based pharmacy? Do you know
23 that?

24 A. I don't know.

1 MR. BARKER: Object to form.

2 BY MR. JANUSH:

3 Q. Okay. And Greg is asking
4 Shweta Raval, "Hi Shweta, can you please
5 pull an 867 report for the customer," and
6 provided Injured Workers Pharmacy
7 information. Do you see that?

8 I'm putting it on the
9 monitor.

10 A. Yep.

11 Q. Okay. And then -- that's on
12 April 16, 2013, right?

13 A. Yes.

14 Q. And nine days later you're
15 following up, "Did we ever review the
16 output of the 867 report," right?

17 A. Yes.

18 Q. And on the tenth day, Greg
19 forwards or says, "Here is the 867 data
20 for the customer, all products including
21 controlled substances."

22 Did I read that right?

23 A. Yes.

24 Q. And your answer on

1 April 29th, which is 13 days after the
2 report was requested to be pulled, "Not
3 quite sure what I'm looking at, but
4 seeing high volume of CS with tramadol
5 and Flexeril has me wanted to know more."

6 Did I read that right?

7 A. Yes, you did.

8 Q. Okay. All right. What did
9 you do when you wanted to learn more, if
10 anything?

11 MR. BARKER: Object to form.

12 THE WITNESS: Typically we
13 review it at the monthly
14 compliance meeting or we'd have a
15 meeting to review it. And I don't
16 recall exactly for this, what was
17 done.

18 BY MR. JANUSH:

19 Q. We -- we couldn't find
20 anything in your production, in your
21 company's production that addressed the
22 outcome of this investigation.

23 Would it be typical to have
24 a memo memorializing when a customer

1 raised a red flag of concern significant
2 enough to populate over a year of 867
3 data to review that customer?

4 MR. BARKER: Object to form.

5 THE WITNESS: It was not our
6 current procedure to document
7 these -- like I said, I was at a
8 meeting where they were showing
9 the number of shipments and my
10 request for more information. It
11 wasn't, like, an order was picked
12 up as questionable. So it was not
13 related to an order. Orders are
14 documented, the investigation and
15 justification. This was just a
16 question that provided me
17 additional information. And
18 obviously we did not reply via
19 e-mail with our resolution.

20 (Document marked for
21 identification as Exhibit
22 Dempsey-9.)

23 BY MR. JANUSH:

24 Q. I'm going to move on to

1 Exhibit 9. This is a document that was
2 from your custodial file production. The
3 cover is Janssen Pharmaceutical Companies
4 of Johnson & Johnson. And the title on
5 Page 1 is "Suspicious Order Monitoring,
6 May 2015, JOM SOM Program."

7 Did you personally create
8 this slide deck?

9 A. I'm looking at the slides.
10 This is the slide deck that I prepared.

11 Q. Okay. Page 2.

12 I should have read into the
13 record by the way, the Bates number.
14 It's JAN-MS-02985441.

15 Turning to Page 2. Title,
16 "JOM Suspicious Order Monitoring."

17 Can you read the first
18 bullet?

19 A. "Companies are required to
20 design and operate a system that would
21 detect suspicious orders and report those
22 suspicious orders to DEA."

23 Q. Okay. And you agree with
24 that requirement, right?

1 MR. BARKER: Object to form.

2 BY MR. JANUSH:

3 Q. I can ask it differently.

4 Do you agree with that
5 statement?

6 A. Yes.

7 Q. And you noted that JOM
8 program was initiated in 2006 is that
9 right?

10 A. That is when we initiated
11 the BW report.

12 Q. Okay. And you further
13 note -- and I'm going to try to get
14 through this as quickly as I can. It's a
15 long document. But I only have like
16 eight areas to cover with you.

17 That -- "From 2006 through
18 first quarter of 2012, the program
19 involved using SAP to monitor historical
20 ordering patterns and flagging orders
21 exceeding three times the 12-month
22 rolling average."

23 Is that right?

24 A. Yes.

1 Q. Okay. And QA is, what,
2 quality assurance?

3 A. Yes.

4 Q. And quality assurance falls
5 under what team?

6 A. Quality assurance reports up
7 through to the quality officer, the chief
8 quality officer of J&J Supply Chain.

9 Q. And is that under JOM?

10 A. No. Quality has their own
11 separate reporting organization that goes
12 up to Johnson & Johnson Supply Chain,
13 leadership.

14 Q. So when you said reports
15 to --

16 A. They don't report to the
17 local operations leadership. They're a
18 separate -- separate entity for that
19 independent oversight, the quality that
20 FDA requires as well, you know.

21 Q. So a quality assurance group
22 worked with customer service between
23 '06 -- 2006 and first quarter of 2012, to
24 complete investigation on each flagged

1 order; is that right?

2 A. As the overseer of the
3 compliance program, if there was ever a
4 questionable order, it was -- QA were the
5 ones that would determine whether the
6 justification deemed it not suspicious
7 and the order could be released. So
8 that -- they did work with customer
9 service to complete all of the
10 investigations on any questionable order.

11 Q. How did you have personal
12 knowledge of this since you only started
13 in March of 2012? How do you have
14 knowledge of what occurred between '06
15 and first quarter 2012?

16 A. The quality leadership was
17 still there.

18 Q. So someone else conveyed to
19 you what --

20 A. They transferred the process
21 to DEA compliance.

22 Q. Okay. And so to be clear,
23 quality assurance was reporting up to the
24 parent company, Johnson & Johnson, on its

1 work; is that right?

2 MR. BARKER: Object to form.

3 THE WITNESS: I know how
4 they're currently organized
5 reporting. But I don't -- to your
6 point, during this time period, I
7 don't know who they reported in
8 to.

9 BY MR. JANUSH:

10 Q. I thought --

11 A. But right now, I apologize,
12 I do know where quality reports now. And
13 I don't know back then in 2006 what the
14 organization reporting structure was.

15 Q. Okay.

16 A. But it was separate from the
17 site leadership. I do know that.

18 Q. Skip ahead to second quarter
19 2012. "New controlled substance
20 compliance group in place, benchmarked
21 with Purdue, Actavis, and Watson for best
22 practices."

23 That -- we've seen one
24 benchmarking memo, the notes in Purdue,

1 right?

2 A. Mm-hmm.

3 Q. Do you have notes from
4 benchmarking with Actavis and Watson?

5 A. I don't know if I took
6 notes. But it was -- it wasn't two
7 separate companies. It was Actavis
8 Watson at the time.

9 Q. You don't recall if you took
10 notes?

11 A. It was more informal.

12 Q. Okay. What did you learn
13 from Actavis and Watson?

14 A. We discussed their
15 algorithm, what kind of algorithm they
16 had.

17 Q. What did they have?

18 A. They used the Buzzeo system.
19 But we didn't go into detail about what
20 it was set up with and all that stuff.

21 Q. And then you wrote,
22 "Developed SOM questionnaire in May."

23 This is referring to your
24 know your customer questionnaire; is that

1 right?

2 A. Yes.

3 Q. And you noted that you
4 received most of the completed
5 questionnaires by end of the year; is
6 that right?

7 A. Yes.

8 Q. And then, "January 2013,
9 initiated first monthly compliance review
10 meeting, and by first quarter to second
11 quarter 2013 revised all standard
12 operating procedures related to
13 suspicious order monitoring and created
14 VSM in preparation for walking through
15 process with DEA if asked at KDC
16 inspection."

17 Did I read that right?

18 A. Yes.

19 Q. Okay. Now, let's just take
20 it through. So from -- up through second
21 quarter of 2013, you'd agree with me,
22 would you not, that the program, the
23 suspicious order monitoring program SAP
24 program, or SAP program, still used three

1 times the 12-month rolling average to
2 flag a suspicious order based on
3 particular SKUs or SKUs, true?

4 A. Yes.

5 Q. Okay. And then on Slide 3,
6 you address some of the things that
7 Mr. Jack Crowley spoke with you about in
8 your meeting. "Meet monthly with a
9 standing agenda." You talked about that,
10 right?

11 A. Yes.

12 Q. "Follow up actions from
13 prior meetings." Discussed that, right?

14 A. Yes.

15 Q. "Metric review and trend
16 review and current events." Addressed
17 all that, right?

18 A. Yes.

19 Q. And this seems to be
20 addressing that, "On metrics, monthly CS
21 orders, number monitored, lack of
22 12-month history, and number flagged."

23 What were you looking at
24 here?

1 A. So at that time if a
2 customer hadn't ordered that SKU in over
3 12 months, when they go in to order
4 again, it would automatically be flagged
5 as questionable because we -- over the
6 12-month period they hadn't ordered it.

7 But then we would go back to
8 the ordering pattern and see they
9 typically order every 18 months, do the
10 investigation, discuss it with the
11 customer, and then we'd release the
12 order.

13 Q. Okay. And, "Quarterly
14 performance, percent of CS to non CS,"
15 this referred to what you testified about
16 earlier today, that on a quarterly basis
17 you'd look at your wholesaler customers
18 percent of controlled substance purchases
19 to their percent of non-controlled
20 substance purchases; is that right?

21 A. Yes.

22 Q. Not a realtime issue though,
23 right?

24 A. No.

1 Q. Okay. And when we speak
2 about quarterly trending. Here's a
3 dashboard that was created after you
4 started as compliance director or
5 director of controlled substance
6 compliance; is that right?

7 A. Yes.

8 Q. And this shows, for example,
9 Cardinal Distribution Inc. over time by
10 quarter, their percentage of scheduled
11 orders, as well as -- well, actually it's
12 Schedule II, Schedule III, tramadol, and
13 a combination of all scheduled products
14 being tracked; is that right?

15 A. Yes. Tramadol was not a
16 scheduled controlled substance at the
17 time; however, in Kentucky they did
18 control it, so we do include it in our
19 suspicious order monitoring program.

20 Q. Okay. Now, I want you to
21 flip forward to Page 9. And Page 9 is
22 the JOM controlled substance order
23 processing; is that right? This is the
24 flowchart for how an order is processed?

1 A. Yes.

2 Q. Okay. And since we're
3 speaking about suspicious orders, I want
4 to focus on -- I'm going to circle it --
5 "Order flagged and forwarded to quality."
6 And then there's the DS SOP 1235.
7 "Follow DS-WI" -- I think that's 3824,
8 but it's really hard to read.

9 A. It's 3824.

10 Q. Okay. Thank you. And we'd
11 have to flip the page to see the rest of
12 the flowchart for happens next; is that
13 right?

14 A. Yes.

15 Q. Because what the next
16 flowchart gives us is specific to a
17 controlled substance flagged order; is
18 that right?

19 A. Yes.

20 Q. You received the order from
21 the customer for Schedule II product.
22 The next step is run DEA unusual quantity
23 report per DS-WI3824; is that right?

24 A. Yes.

1 Q. And running the DEA unusual
2 order quantity report is your
3 mathematical formula of three times or
4 300 percent the average rolling weekly --

5 A. Monthly.

6 Q. -- monthly order. So you're
7 comparing that given day's order that was
8 flagged to what?

9 A. To the last average monthly
10 ordering pattern for 12 months. So we
11 take the average of 12 months, times it
12 by three.

13 Q. Okay. Incidentally, do you
14 know where the three times historical
15 average order came from at the DEA level
16 originated from?

17 A. The List I chemical
18 guidelines for CMEA, which was the only
19 information available in regards to
20 thresholds.

21 Q. It didn't apply to opioid
22 products though, right, it was about
23 List I chemicals?

24 A. It was a guidance that DEA

1 provided the pharmaceutical companies
2 that produce list chemicals. And DEA
3 didn't provide guidance on controlled
4 substances. So we went with the guidance
5 that was available, that DEA provided.

6 Q. On a totally different
7 matter.

8 MR. BARKER: Object to form.

9 BY MR. JANUSH:

10 Q. Right?

11 A. At the time that the
12 thresholds were presented, there was a
13 serious issue. It was right after this
14 Combat Methamphetamine Act came out. So
15 List I chemicals, there was a serious
16 issue.

17 Q. What does that mean?

18 A. There was a serious meth
19 issue in the country at the time that
20 these thresholds came out, and that is
21 why DEA provided guidance to wholesalers
22 and handlers of pseudoephedrine products
23 on what they should be -- what thresholds
24 should be used when monitoring orders.

1 Q. So your position is the DEA
2 told Janssen or JOM to utilize
3 300 percent of the average monthly or
4 annual monthly order to set its threshold
5 for suspicious order monitoring?

6 A. No. DEA did not tell us
7 what to set our thresholds for. However,
8 we wanted to use information that was out
9 there, and DEA did provide this to
10 registrants that handled List I
11 chemicals.

12 In 2013 -- actually in 2007,
13 we reviewed it with the DEA. In 2013, we
14 once again reviewed it, our whole
15 program, with DEA. So they were aware
16 that we were using this List I threshold
17 in our suspicious order monitoring
18 program.

19 In every inspection they
20 would take our SOPs with them.

21 Q. You are talking about a
22 plant inspection?

23 A. I'm talking about the
24 distribution license inspections where

1 they come in and they determine whether
2 effective control is in place to prevent
3 diversion and abuse.

4 So besides reviewing all of
5 the security systems that you have in
6 place, the cameras, the alarms, they do
7 review suspicious order monitoring to
8 make sure that your system is adequate.
9 And so they request our procedures.

10 And in 2013, we specifically
11 sat down with Kentucky diversion
12 investigators, they did the inspection.
13 And we provided them the whole program,
14 these flow diagrams, that showed this is
15 how we -- we monitor our orders.

16 Q. And -- and who did you meet
17 with and provide this to?

18 A. In 2013, it was diversion
19 investigators Billy Lane and Jason, I
20 apologize, I forget Jason's last name.
21 But we can follow up with that.

22 Q. And what about earlier?

23 A. I do recall a regulatory
24 contact -- regulatory agency contact

1 report that was provided by a previous
2 DEA compliance person for JOM, where in
3 2007 he reached out to a California
4 diversion investigator, a supervisor, and
5 he relayed our three times the rolling
6 12-month average to that -- I believe it
7 was -- I forget which district out of
8 California. So that's the earliest that
9 I'm aware of that the three times was
10 given to DEA.

11 But they have -- in 2008,
12 they took our SOP from the Newark office,
13 came into our New Jersey distribution
14 center, and they took our suspicious
15 order monitoring SOPs. And that's a
16 routine request, along with all of
17 your -- they ask for all of your SOPs
18 around handling controlled substances and
19 including suspicious order monitoring,
20 has been a request.

21 Q. Do you have memos of those
22 meetings?

23 A. Yes.

24 MR. JANUSH: We call for the

1 production of any memos concerning
2 the testimony just provided.

3 MR. BARKER: They've been
4 produced.

5 MR. JANUSH: You're making a
6 statement on the record that memos
7 have been produced where employees
8 at JOM have confirmed that they
9 handed over SOM, suspicious order
10 monitoring protocols to the DEA?

11 MR. BARKER: The
12 documentation relating to those
13 meetings has been produced.

14 BY MR. JANUSH:

15 Q. Let's go back to the
16 flowchart and address. So we talked
17 about that the math would be run at three
18 times the annual average. Then you'd
19 open a DEA unusual order quality report
20 query; is that right?

21 A. Quantity report.

22 Q. Right. Sorry. Order
23 quantity report query -- query.

24 And going below, if the

1 order exceeded the minimum order quantity
2 and is above three times the calculated
3 12-month per weekly order average, it
4 would go to customer service, who would
5 reach out to the customer to obtain a
6 reason for the increase; is that right?

7 A. That's what -- that's what
8 it reads.

9 Q. And then from there,
10 ValueTrak report would be run to compare
11 inventory to the demand of the increase?

12 A. So that, as earlier
13 explained, customer service or the
14 planning, after they engage with the
15 customer, they have a defined script,
16 when -- when there is a questionable
17 order. We want to make sure that we're
18 asking the same question, no matter what
19 the customer. And part of the
20 investigation is to use that 852 and 867
21 data to the best that we could to
22 determine whether that questionable order
23 made sense or if there's some unplanned
24 change in their demand that they didn't

1 communicate to us.

2 Q. Is it your position that in
3 and after April 2013, the date of this
4 document, ValueTrak reports were being
5 run for every questionable order?

6 MR. BARKER: Object to form.
7 Evan, you're ending your questions
8 in kind of an odd place and I
9 think the witness is having
10 trouble following you there.

11 MR. JANUSH: That's okay.

12 THE WITNESS: So as of this
13 flow diagram, the SOP stated that
14 they would have to run and get the
15 852 and 867 data, the channel ops,
16 the planners would.

17 BY MR. JANUSH:

18 Q. But you know in -- in
19 reality that wasn't happening for every
20 suspicious order, right?

21 MR. BARKER: Object to form.

22 THE WITNESS: I do not
23 believe that's true. Any order
24 that is questionable was

1 investigated, and they did this
2 activity.

3 BY MR. JANUSH:

4 Q. And where would the
5 documentation be kept at JOM showing that
6 the ValueTrak report was run to compare
7 to inventory for every order that was
8 exceeding the minimum order quantity and
9 above three times the calculated 12-month
10 weekly -- per weekly order average?

11 A. Customer service had a share
12 point where they stored all this
13 information.

14 Q. And that customer service
15 was with which company?

16 A. JOM.

17 Q. Okay. So somewhere at JOM,
18 within a customer service share point,
19 outside of the suspicious order
20 monitoring share point, would be a folder
21 area where all of the ValueTrak analysis
22 would exist for every order that exceeded
23 the minimum order mathematical formula?

24 MR. BARKER: Object to form.

1 THE WITNESS: The -- I'm not
2 quite -- I do not understand what
3 you mean by suspicious order
4 monitoring share point. The --

5 BY MR. JANUSH:

6 Q. So there's a suspicious
7 order monitoring share point, I'm going
8 to represent to you that we have been
9 produced documents from, at Janssen. Do
10 you understand that?

11 A. Yes. There are -- there's
12 several share points that are involved in
13 the program.

14 Q. Okay.

15 A. So I just wanted to say that
16 suspicious order monitoring share point
17 is owned by channel ops, the planners.
18 Customer service had their share point
19 that they maintained the metrics and
20 these -- this documentation.

21 Q. Okay. So customer service
22 has a separate share point that falls
23 outside of suspicious order monitoring
24 share point, at which internal folks at

1 Janssen can pull up the ValueTrak report
2 that was run for every suspicious order
3 that exceeded the minimum order quantity
4 and was above the three times the
5 calculated 12-month per weekly order
6 average; is that right?

7 A. As I am aware, there is a
8 C-II metrics folder that retains all of
9 the correspondence with the customer, as
10 well as the reports that were run from
11 ValueTrak for all of the questionable
12 orders.

13 Q. Did you assist in -- in
14 seeking to locate such information for
15 production in this case?

16 MR. BARKER: Objection.

17 MR. JANUSH: I'm not going
18 to --

19 MR. BARKER: Object to form.
20 I'll let her answer that question,
21 as long as you agree that her
22 answer is not a waiver of attorney
23 work product or attorney/client
24 communications.

1 MR. JANUSH: I agree
2 entirely.

3 MR. BARKER: She can answer
4 that question with that
5 understanding that there is no
6 waiver.

7 MR. JANUSH: No waiver.

8 THE WITNESS: I did direct
9 the lawyers to these share points
10 that contain this information.

11 MR. JANUSH: Okay. We'll
12 deal with after this deposition
13 where these ValueTrak reports are
14 and where the customer service
15 investigation notes are concerning
16 each suspicious order.

17 I haven't been able to
18 locate them. I'm just putting
19 that on the record.

20 BY MR. JANUSH:

21 Q. Next step is that JOM DEA
22 compliance team makes a determination; is
23 that right?

24 A. Yes.

1 Q. It either notifies that the
2 order will be canceled and not shipped,
3 or it determines that the order can
4 proceed or be reduced. Those are the two
5 decision points here; is that correct?

6 A. Yes.

7 MR. BARKER: Object to form.

8 BY MR. JANUSH:

9 Q. Okay. And if it decides,
10 the DEA compliance team, that the
11 customer needs to be notified the order
12 will be canceled and not shipped, the
13 last step here is, "JOM compliance
14 determines whether DEA notification is
15 required."

16 Am I reading that right?

17 A. Yes.

18 Q. However, if a manufacturer
19 utilizing a suspicious order monitoring
20 program determines that an order was
21 suspicious enough that it could not be
22 shipped, it has a duty to notify the DEA
23 of that fact, doesn't it?

24 A. If there was-- we had been

1 instructed over the years with DEA with
2 our encounters, that if there is an order
3 that's truly suspicious they want to know
4 about it. They don't -- do not want to
5 know every order that's been reviewed.
6 They call that excessive.

7 So if it was truly deemed
8 suspicious, we have been told to notify
9 them.

10 Q. So we're on the same page.
11 Here you are addressing in a workflow
12 that if the compliance team deems the
13 order to be canceled and not be shipped,
14 it notifies the customer, and that JOM
15 DEA compliance determines whether DEA
16 notification is required.

17 A. Yes.

18 Q. But if an order is deemed
19 suspicious enough to be not shipped,
20 you've determined that it's suspicious,
21 no?

22 A. No. It depends. I mean,
23 you could have a customer -- and we've
24 had these cases, where the national

1 distribution center normally does the
2 ordering. But then some local
3 distributor, who goes in and orders
4 stuff, it gets monitored because they
5 don't typically order, it goes to the
6 national hub.

7 And so we go through our
8 entire process. You know, we run the
9 ValueTrak, see that it doesn't go there.
10 And then when it gets to be here, we
11 notify the customer. Working with the
12 customer, they tell us, "Oh, it's a
13 training error. The person shouldn't
14 have submitted that order." In which
15 case, that is not a suspicious order, and
16 we're not required to report to DEA. So
17 there's lots of different types of orders
18 that come in.

19 Q. Got it.

20 A. And just -- you know, and
21 that's an example. We did -- you know,
22 recently reach out to DEA and said, you
23 know, if there's a training error and
24 somebody placed an order that got flagged

1 in our system and we followed up, and
2 they said, "Oh, that was a training
3 issue. The national potential hub is
4 supposed to receive it," to cancel the
5 order.

6 So we asked DEA, "Do we
7 report those?" And we were instructed
8 that's nice information to have, but it's
9 not a requirement to report.

10 Q. So when you have a situation
11 like a training error, or conversely a
12 worse situation like a truly suspicious
13 order, your JOM DEA compliance team
14 documents that investigation, doesn't it?

15 A. Yes.

16 Q. Okay. So I'm going to
17 circle that last box here, one of those
18 last boxes here. And I'm going to ask
19 and write here, "Where is the
20 documentation?" And your answer is what?
21 Where is the documentation at this step
22 maintained?

23 MR. BARKER: Object. Object
24 to the demonstrative.

1 THE WITNESS: So if there is
2 communication with DEA, we use our
3 regulatory agency contact reports.

4 So if there was any
5 discussion around an order that
6 was questionable, we would use
7 that tool to document the actual
8 discussion with DEA.

9 And then --

10 BY MR. JANUSH:

11 Q. What tool is that?

12 A. It's Regulatory Agency
13 Contact Report. We call it RACR for
14 short.

15 Q. Okay.

16 A. So there would be a RACR
17 report of a discussion with DEA.

18 The actual documentation for
19 the investigation, as I mentioned before,
20 would be maintained on the customer
21 service SharePoint.

22 Q. Okay. So let's move forward
23 to Page 15. And looking at this
24 SharePoint, suspicious order monitoring

1 SharePoint, is there any folder here
2 where that information concerning a
3 suspicious order investigation or report
4 would be maintained?

5 MR. BARKER: Object to form.

6 THE WITNESS: So if you look
7 above the word "suspicious order
8 monitoring."

9 BY MR. JANUSH:

10 Q. Yep.

11 A. It shows "channel ops."

12 Q. Sure.

13 A. So channel ops are the
14 planners that work with the big
15 wholesalers. And this -- when we were
16 doing our questionnaires, we -- channel
17 ops as well as trade, engage with the
18 wholesalers to get these questionnaires
19 done. So channel ops made this
20 SharePoint specifically for the
21 questionnaires for them to upload. It is
22 not what we deem our order monitoring
23 compliance SharePoint.

24 This is -- you know, this is

1 their SharePoint. And they kept track of
2 the questionnaire documentation they
3 received from the customers. Because
4 they are the ones that had the more
5 day-to-day interaction with the customers
6 and were able to get the questionnaires
7 completed.

8 Q. So what do you consider your
9 order monitoring compliance SharePoint?

10 A. The C-II, right here. The
11 following one. The customer service
12 Schedule II.

13 Q. Schedule II metrics
14 SharePoint?

15 A. Yes. That is our --

16 Q. And what would the folder be
17 called in Schedule II SharePoint where we
18 would find these reports?

19 MR. BARKER: Object to form.

20 THE WITNESS: Well, this was
21 in -- from 2014. That -- there
22 has been an updated document
23 folder, where we are adding it,
24 we're adding the justification on

1 there.

2 BY MR. JANUSH:

3 Q. And what would it be called?

4 MR. BARKER: Object to form.

5 THE WITNESS: The actual
6 wording, I don't have it in front
7 of me.

8 BY MR. JANUSH:

9 Q. So I'm going -- I'm going to
10 represent to you that we've received a --
11 what's called a noncustodial production
12 in this case of the suspicious order
13 monitoring SharePoint, but have never
14 received a production from the
15 noncustodial SharePoint called Schedule
16 II SharePoint. So that's why I'm asking
17 all these probing questions.

18 A. Well, one thing -- this is
19 how it looked at 2014. Since then, we've
20 included a lot of enhancements through
21 the benchmarking.

22 And we -- in later 2013, we
23 identified that we wanted to do a folder
24 for SharePoint. So I don't recall if

1 this shared documents is where they put
2 it.

3 Q. Okay.

4 A. I mean --

5 Q. But if someone looked --

6 A. -- it's been more organized
7 since then.

8 Q. If someone looked hard
9 enough, they'd be able to find the folder
10 where your customer service group
11 documented each investigation into a
12 potentially suspicious order; is that
13 right?

14 MR. BARKER: Object to form.

15 THE WITNESS: The
16 documentation for each order
17 release was documented and stored.
18 I just -- I just don't know where
19 it was stored under -- at this
20 time in 2014.

21 BY MR. JANUSH:

22 Q. Okay.

23 A. I do know, 2018, I know
24 where the documentation is stored.

1 Q. Where's that?

2 A. It is on this -- this --
3 since 2014, it's been migrated to
4 Microsoft 365. It's a whole new
5 SharePoint, and there's more information.
6 There's also the justification forms.
7 All the -- there's a tab for
8 justification forms, which come from the
9 customer for all the monitor orders.

10 So it's in there now.

11 Q. And how far back does your
12 data go storing documents concerning
13 prior investigations of suspicious
14 orders?

15 A. Our record retention for DEA
16 records is two years. However, we do
17 have records back to 2014.

18 Q. Who would be a point person,
19 key custodian for the SharePoint files
20 that fall outside of the suspicious order
21 monitoring SharePoint but would capture
22 these investigation memos?

23 MR. BARKER: Object to form.

24 THE WITNESS: The

1 investigation documentation was
2 maintained by the customer service
3 department.

4 BY MR. JANUSH:

5 Q. Can you name a key person in
6 the customer service department, if I
7 were to want to depose them and learn
8 more about where these documents are, who
9 would that person be?

10 A. Raphaela Figgallri. She's
11 the -- she would have -- she was the one
12 that would have all the documentation for
13 most of the order releases.

14 Q. But only from 2014 forward?

15 A. Yes.

16 MR. BARKER: If you're
17 asking whether --

18 MR. JANUSH: I don't need
19 to -- we can go off the record for
20 a moment to have a discussion.

21 THE VIDEOGRAPHER: The time
22 is 1:31 p.m. We are going off the
23 record.

24 (Lunch break.)

1 THE VIDEOGRAPHER: We are
2 back on the record. The time is
3 2:38 p.m.

4 BY MR. JANUSH:

5 Q. Hello, Ms. Dempsey.

6 I'm going to hand you what's
7 been marked as Exhibit 10.

8 (Document marked for
9 identification as Exhibit
10 Dempsey-10.)

11 BY MR. JANUSH:

12 Q. And it's going to look a
13 little familiar to you, because it's
14 similar to a string, an e-mail string
15 that we were addressing earlier regarding
16 communications between you and Ron Kuntz
17 regarding red flag issues like
18 prescribers of interest. Do you remember
19 that discussion a while back?

20 MR. BARKER: Object to form.

21 THE WITNESS: I recall that
22 we discussed it.

23 BY MR. JANUSH:

24 Q. Okay. So, and that's on

1 Page 2 of this e-mail where --

2 "Greetings, Ron. Every month JOM and DEA
3 team review orders" --

4 I'm sorry. I should do the
5 Bates into the record. It's
6 JAN-MS-00421189.

7 "Every month JOM and DEA
8 team review orders. This month we
9 reviewed recent HDMA slide deck HD Smith
10 provided. If you look at Page 13, there
11 is a slide on six components. The group
12 wanted to know if you knew if the Nucynta
13 team keeps track" -- "keeps tab on the
14 following three items:

15 "Number 3: Cash and
16 insurance payment trends.

17 "Number 5: Top 10
18 prescriber analysis.

19 "And Number 6: Individual
20 analysis of prescribers of interest.

21 "What are your thoughts
22 about an idea I had that we perhaps do a
23 training deck for the Nucynta sales force
24 on the red flags shown in the HD Smith

1 deck?"

2 Did I read that accurately?

3 A. Yes, you did.

4 Q. Okay. So earlier I
5 addressed this -- this topic of high
6 prescribers being analyzed as a red flag
7 issue. And here it's made more clear
8 that it's being addressed as a red flag
9 issue in the recent HDMA -- that's the --
10 the Healthcare Distributors Association;
11 is that right?

12 MR. BARKER: Object to form.

13 THE WITNESS: Healthcare
14 Distribution Management
15 Association.

16 BY MR. JANUSH:

17 Q. Okay. And now, that name
18 has been changed to HDA today, right?

19 A. Healthcare Distribution
20 Association, yes.

21 Q. Okay. And so this is
22 referring to a slide deck that HDMA
23 created that HD Smith provided to you; is
24 that right?

1 MR. BARKER: Object to form.

2 THE WITNESS: HD Smith, who
3 was one of our wholesalers --

4 BY MR. JANUSH:

5 Q. This --

6 A. -- that we provided, they
7 presented at HDA and after you attend
8 their conferences you have access to the
9 slide deck that was presented during the
10 conferences.

11 Q. Got it. So HD Smith --

12 A. They presented at the
13 conference.

14 Q. -- presented at a conference
15 and provided you with their slide deck;
16 is that right?

17 A. No. HD Smith did not give
18 us the slide deck. HDA posts the
19 presentations that are given and we went
20 online and retrieved the presentation
21 from the HDMA website.

22 Q. Great. How would you go
23 about retrieving slide decks from HDMA
24 presentations?

1 A. When you typically attend
2 the conferences, at the end, they e-mail
3 you with links to the conference
4 presentation matter.

5 Q. How many HDA conferences
6 would you say you've attended throughout
7 your years working with JOM or Janssen?

8 A. I believe I have attended
9 four of the March conferences.

10 Q. Is there something specific
11 about a March conference, is that the
12 annual conference?

13 A. Yes. At the March
14 conference, that is more of a focus on
15 the regulatory, you know, so I go -- DEA
16 speaks at that March conference. DEA has
17 a booth at the -- on the floor of the
18 conference. So, you know, you listen to
19 DEA. Plus you can -- during your break
20 while you are looking at all the vendors,
21 policy and liaison is there if you want
22 to approach them and discuss issues.

23 They also have state and
24 federal regulations around handling

1 controlled substances they report out on,
2 as well as security, supply chain
3 security, what kind of theft, GPS,
4 FreightWatch, any of the various controls
5 that are the best practices for securing
6 your product to your customer.

7 So DEA compliance would go
8 to this session, as opposed to other
9 sessions which have different focuses.

10 Q. Okay. And at this session,
11 six red flag components were presented
12 within the HD Smith slide deck; is that
13 right?

14 MR. BARKER: Object to the
15 form.

16 Do you want to give the
17 witness an opportunity to review
18 it?

19 THE WITNESS: It's not
20 attached. It's not attached.

21 BY MR. JANUSH:

22 Q. It's the e-mail that I'm
23 addressing.

24 A. Right.

1 Q. "This month we reviewed
2 recent HDMA slide deck HD Smith provided.
3 If you look at Page 13, there is a slide
4 on six components.

5 "The group wanted to know if
6 you knew if the Nucynta team keeps tab on
7 the following three items."

8 So I'm assuming these are
9 three of the six red flag components; is
10 that right?

11 MR. BARKER: Object to form.

12 THE WITNESS: For our
13 customer, the wholesaler, they
14 presented on their six components,
15 and I copied the three that I
16 wanted to ask Ron about.

17 BY MR. JANUSH:

18 Q. And when we say -- when you
19 wrote, "The group wanted to know if you
20 knew if the Nucynta team keeps tab on the
21 following three items," who is the group
22 that wanted to know if Ron Kuntz knew if
23 Nucynta team keeps tab on these three
24 items?

1 A. The suspicious order
2 monitoring compliance group, which was
3 customer service and DEA compliance.

4 Q. Okay. So customer service
5 and DEA compliance at JOM, right?

6 A. Yes.

7 Q. Wanted to know if Ron Kuntz
8 knew whether the Nucynta team keeps track
9 of cash and insurance payment trends,
10 right?

11 A. Yes.

12 Q. Keeps track of ten top
13 prescriber analysis, right?

14 A. Yes.

15 Q. And keeps track of
16 individual analysis of prescribers of
17 interest; is that right?

18 A. Yes.

19 Q. And Ron didn't answer you in
20 writing, at least in this e-mail string,
21 he didn't answer your questions. He
22 instead invited a visit with you, didn't
23 he?

24 MR. BARKER: Object to form.

1 BY MR. JANUSH:

2 Q. You can take time to review
3 the e-mail. But I can't find his
4 answers. You asked a pretty
5 straightforward question, didn't you?

6 A. Yes, I did.

7 Q. His answer was, "Hi,
8 Michele. Long time, no see. Sorry to
9 take so long to get back to you." And I
10 emphasize because there are three so in
11 the "so."

12 "I would really like to meet
13 with you to discuss this topic. We are
14 working on some ideas and you may be able
15 to provide some very good insights. When
16 do you think you can come up to T-Ville?"

17 Did I read that right?

18 A. Yes.

19 Q. Did you ever get up to
20 T-Ville?

21 A. I believe I believe we did
22 meet because that precipitated the other
23 e-mail that we reviewed where I forwarded
24 him information. So we met about --

1 overall in the general, and he asked if
2 there was anybody that I knew that could
3 help. And that's why I forwarded Jack
4 Crowley's information to him.

5 Q. And what was the answer as
6 to -- that Ron eventually gave you, if
7 any, as to whether the Nucynta team was
8 keeping track of cash and insurance
9 payment trends, the top ten prescriber
10 analysis, and individual analysis of
11 prescribers of interest?

12 A. I don't recall.

13 Q. Moving over to the next page
14 of this document, there's an
15 attachment -- or not attachment. An
16 e-mail from April 8, 2013, and a string
17 titled, "Suspicious order monitoring
18 monthly review agenda."

19 A. Monthly compliance review.

20 Q. "Monthly compliance review
21 agenda." Right. Zooming out. I'm
22 trying to do two things at once here.

23 Okay. And I want you to
24 turn your attention to trend review at

1 Number 3.

2 Do you see that?

3 A. Yes.

4 Q. And it looks like the
5 Walgreens Perrysburg, Ohio was facing
6 immediate suspension. And incidentally,
7 do you know -- do you know who wrote this
8 review?

9 MR. BARKER: Object to form.

10 THE WITNESS: These are
11 notes that I took during the
12 meeting.

13 BY MR. JANUSH:

14 Q. You wrote this review,
15 right?

16 A. Yes.

17 Q. You wrote this? You wrote
18 the e-mail and transmitted it; is that
19 right?

20 A. Yes.

21 Q. Okay. And you're saying,
22 "We will block them, Walgreens,
23 Perrysburg, from ordering CS once we get
24 official notification." And then it

1 looks like you have an update here. And
2 I'm sure if we saw this in a string with
3 color, we'd see comments, "Update, DEA
4 has not pulled their registration at this
5 time, so SAP master data cannot be
6 modified to prevent shipping to them.
7 Court case still underway. Action, none
8 until court case is over."

9 Did I read that right?

10 A. Yes.

11 Q. Okay. Why would JOM or
12 Janssen block -- not block Walgreens that
13 was facing an imminent suspension until
14 the official notification came?

15 A. We -- when we say official
16 notification, that is when they lose
17 their DEA license.

18 We did not ship directly to
19 Walgreens. We supplied the wholesalers.

20 So we were -- we were
21 monitoring the situation to see if DEA
22 pulls that registration, in which case we
23 would communicate with our customers, the
24 wholesalers, to make sure that they were

1 not shipping to our location that did not
2 have a valid DEA license to handle and
3 distribute controlled substances.

4 Q. So if you were not shipping
5 to Walgreens, Perrysburg, how would
6 you -- were you in a position to write,
7 "We will block them from ordering CS once
8 we get official notification"?

9 A. If we knew that they lost
10 their license, we would have -- we would
11 have made sure that the wholesalers were
12 not shipping to that location.

13 Q. But you know in practical --
14 in practical terms, that that's not how
15 it worked, right?

16 MR. BARKER: Object to form.
17 BY MR. JANUSH:

18 Q. You know what really
19 happened when a site was shut down by the
20 DEA, right? I mean, let's talk turkey
21 about what actually happened in practice.

22 MR. BARKER: Object to form.

23 Is there a question?

24 THE WITNESS: Could you

1 explain?

2 BY MR. JANUSH:

3 Q. Sure. You know, that what
4 would really happen is it would be
5 business as usual, and a Walgreens
6 central distribution center would just
7 handle all of the distribution of
8 controlled substances to make sure that
9 Janssen's products remained unaffected in
10 terms of -- unaffected in the chain of
11 commerce. You know that, right?

12 MR. BARKER: Object to form.

13 THE WITNESS: I do know that
14 we had had cases in the past where
15 we engaged DEA when there was an
16 investigation of a wholesaler. We
17 knew that some of those
18 distribution centers were -- lost
19 their licenses, and they were
20 directing that material to another
21 distribution center that had an
22 active DEA license.

23 And we analyzed the quantity
24 of the order, that it was

1 consistent to what that DC and the
2 other three would have been
3 supplying of our Duragesic and
4 Nucynta, and then we reached out
5 to the DEA of that DC, which was
6 in California.

7 And we reviewed our
8 rationale to explain, here is the
9 situation, patients need medicine.
10 Our Duragesic needs to go to the
11 patient. We understand that these
12 other DCs have lost their
13 licenses; however, this one
14 located in your California DC
15 still has the license.

16 Is the company in good
17 standing? And these orders do
18 not -- are not suspicious. And we
19 asked him if he agreed with our
20 approach.

21 And he verbally gave his
22 agreement with our approach.

23 BY MR. JANUSH:

24 Q. Well, I'm not sure what

1 question you answered.

2 A. It was for -- a
3 regulatory -- it was RACR where we
4 engaged DEA to review our process,
5 understanding that if there are
6 locations -- a wholesaler has many
7 locations. If there are some locations
8 that have lost their license, I guess you
9 said you -- you were talking a pharmacy
10 level. We don't ship to the pharmacy
11 level.

12 You were giving an example
13 that, well, one Walgreens would lose its
14 license, and they'd ship the inventory to
15 another location. I was giving you an
16 example of our customer, of when a
17 wholesaler has a local DC that loses its
18 license, what we do and how we have
19 reviewed it with DEA, our rationale
20 for -- if there's a license revocation at
21 a DC, how we continue the patient supply
22 of medicine.

23 Q. Okay. I'm going to move on
24 to another exhibit. You know what?

1 Before I do, I just want to ask one
2 follow-up question. Going back to the
3 red flag issue, it's April 8, 2013.
4 You're in about a year and a month as
5 director of controlled substance
6 compliance at Johnson & Johnson or JOM;
7 is that right?

8 A. Yes.

9 Q. And you're asking a
10 marketing guy, Ron Kuntz, who's
11 overseeing the -- the -- a product
12 director for the pain franchise whether
13 the Nucynta team engages in a top ten
14 prescriber analysis to review prescribers
15 that may be of concern, right?

16 MR. BARKER: Object to form.

17 THE WITNESS: As we
18 previously -- before you wanted to
19 know if I knew what the trade
20 analytics had, and I was not aware
21 of that. I went to a conference
22 where one of our customers, HD
23 Smith, presented out on some of
24 the items that they monitor. So I

1 was asking the person that I
2 thought would know if we had this
3 information and if we collected
4 it.

5 BY MR. JANUSH:

6 Q. Shouldn't you have known
7 independently, as the director of
8 compliance, whether, as a matter of
9 substantive compliance, Janssen was
10 tracking the Top 10 prescribers to
11 determine whether there was anything
12 suspicious with their prescribing habits?

13 MR. BARKER: Object to form.

14 THE WITNESS: No. As I
15 stated before, we are transparent
16 with DEA. We go to all the DEA
17 conferences, the distributor
18 conferences. We -- our program,
19 we enhance it to make sure that
20 we're addressing what DEA has
21 asked for. And they never asked
22 us for this information.

23 In all of our reviews and
24 inspections they never told us

1 that they expected us to know this
2 information.

3 MR. JANUSH: For those on
4 the phone I'm just reviewing an
5 exhibit.

6 BY MR. JANUSH:

7 Q. Isn't it true that the DEA
8 was presenting slides, PowerPoint slide
9 decks, at various conferences addressing
10 red flags, factors to consider when
11 operating a suspicious order monitoring
12 program such as, where is your product
13 going, who is it going to, how many other
14 distributors are involved, and who are
15 the downstream customers?

16 MR. BARKER: Object to form.

17 THE WITNESS: DEA has held
18 several different types of
19 conferences. They hold the
20 manufacturing import/export
21 conferences. They hold
22 distributor conferences. They
23 hold pharmaceutical pharmacy
24 awareness. And now they're

1 currently offering practitioner
2 awareness training.

3 So they have gone through
4 all of the -- down the supply
5 chain presenting out.

6 BY MR. JANUSH:

7 Q. And you've never seen a
8 presentation in which the DEA addressed
9 that you need to look at high prescribers
10 as a red flag for -- for an interest
11 group to be monitored?

12 MR. BARKER: Object to form.

13 THE WITNESS: The
14 presentations that mention that
15 were for those distributors that
16 went to pharmacies.

17 BY MR. JANUSH:

18 Q. And you're saying those
19 presentations didn't apply to
20 manufacturers who may have been at the
21 same time as they were selling their
22 drugs to distributors were targeting
23 doctors to -- to write prescriptions of
24 their product?

1 MR. BARKER: Object to form.

2 THE WITNESS: Can you repeat
3 the question you want me to
4 answer?

5 BY MR. JANUSH:

6 Q. Sure.

7 And you're saying those
8 presentations didn't apply to
9 manufacturers who may have been at the
10 same time as they were selling their
11 drugs to distributors, targeting doctors
12 to write prescriptions of their opioid
13 products?

14 MR. BARKER: Object to form.

15 THE WITNESS: I'm saying
16 that those presentations at
17 conferences that DEA held were
18 specific for the licenses that
19 were being held by the
20 participants.

21 So a manufacturing
22 registration, you went to the
23 manufacturing, and they said you
24 need to have a suspicious order

1 monitoring in place. And it
2 specified monitoring your orders.

3 And then if you go to a
4 distributor presentation, they
5 would go into know your customer.

6 And then when you would go
7 to the pharmacy, that's the last
8 line, there's specific
9 requirements and red flags for
10 those.

11 So was there a specific
12 manufacturer know-your-customer
13 downstream? That was never
14 communicated at a DEA conference.
15 And as I mentioned before, it
16 wasn't until the 2017 Mallinckrodt
17 e-mail notification that DEA
18 formally indicated downstream data
19 analysis.

20 THE VIDEOGRAPHER: Where is
21 your microphone clipped? Is it --
22 I want to make sure it's -- there
23 you are. All right. Thank you.

24 (Document marked for

1 identification as Exhibit
2 Dempsey-11.)

3 BY MR. JANUSH:

4 Q. I'm going to hand you what
5 I've marked as Dempsey Exhibit 11.

6 And this is an e-mail from
7 you to John Daly. And it's dated May 6,
8 2014. Its Bates stamp is
9 JAN-MS-03054667.

10 And this appears to be
11 addressing the potential to change the
12 shipment of the Concerta model such that
13 Janssen or Johnson & Johnson would ship
14 the brand directly to St. Louis's
15 Schnucks distribution center where their
16 100 pharmacies will get Concerta. Do I
17 have that right?

18 MR. BARKER: Objection.
19 Object to form.

20 THE WITNESS: This is a
21 potential strategy that commercial
22 was pursuing for our ADHD medicine
23 to go to the pharmacy.

24 BY MR. JANUSH:

1 Q. Okay. And when you say go
2 to the pharmacy, to go direct to
3 pharmacy --

4 A. The distribution center.

5 Q. -- and cut out the
6 wholesaler, right?

7 A. This was a Concerta strategy
8 that was never implemented.

9 Q. Okay. And so I'm not
10 addressing it to get into ADHD or
11 Concerta. I'm addressing it for the
12 second paragraph.

13 Can you read that starting
14 with "problem" and ending with "defense"?

15 A. "Problem is, our SOM program
16 needs to be enhanced significantly to
17 match what the wholesalers do if we are
18 going direct to pharmacies."

19 Q. Keep going.

20 A. "We will no longer have the
21 wholesaler thresholds to be our last line
22 of defense."

23 Q. So what were you
24 communicating to John Daly here about the

1 need to enhance your suspicious order
2 monitoring program significantly to match
3 what the wholesalers do if you were going
4 direct to pharmacies?

5 A. Our customer changes. So
6 the whole due diligence that's required
7 for knowing your customer will now
8 involve going to all 100 pharmacies and
9 doing more due diligence on the end, if
10 we follow this distribution model.

11 Q. And where you wrote, "We
12 will no longer have the wholesaler
13 thresholds to be our last line of
14 defense," what were you referring to
15 there?

16 A. The wholesalers'
17 responsibility as part of their
18 suspicious order monitoring, to monitor
19 the orders that are going to the
20 pharmacies.

21 Q. Did Janssen and JOM rely on
22 wholesaler thresholds as their last line
23 of defense with regard to suspicious
24 order monitoring?

1 MR. BARKER: Object to form.

2 THE WITNESS: No. As part
3 of our due diligence, it was not
4 just their algorithm. It was
5 their onsite visits. It was
6 their -- the compliance, all the
7 onboarding of the -- the
8 pharmacies and their due diligence
9 program.

10 BY MR. JANUSH:

11 Q. I'm not sure I understand.

12 A. What -- what I'm saying
13 is --

14 Q. Hold on one second. Hold on
15 one second. I had a question pending
16 that simply asked, "Did Janssen and JOM
17 rely on wholesaler thresholds as their
18 last line of defense with regard to
19 suspicious order monitoring?"

20 A. No.

21 Q. Well, here you have a
22 statement saying, if you go to -- direct
23 to the pharmacy, "we will no longer have
24 the wholesaler thresholds to be our last

1 line of defense."

2 Did I read that right?

3 MR. BARKER: Object to form.

4 THE WITNESS: At this point,
5 when I was communicating to the
6 Noramco general manager, he had
7 only knowledge of certain aspects
8 of suspicious order monitoring.
9 And that is how I presented it to
10 him.

11 Because Noramco really
12 didn't -- I reported in Noramco
13 and the general manager did not
14 understand all of the details
15 around JOM suspicious order
16 monitoring. But I wanted to relay
17 to him that this would be a
18 significant change and I was
19 asking for support.

20 BY MR. JANUSH:

21 Q. But you haven't answered my
22 question. My question is --

23 A. I cited --

24 Q. -- about -- excuse me? It

1 wasn't about who you were talking to. It
2 really wasn't about the context. It's
3 about the fact that you were stating,
4 declaring, "We will no longer have the
5 wholesaler thresholds to be our last line
6 of" -- "of defense."

7 Do you see that? I'm
8 circling it.

9 A. Yes, I do.

10 Q. You said that, right?

11 A. I wrote that.

12 Q. Okay. And you wrote that in
13 the context of, if you ship brand
14 directly to Schnucks distribution center,
15 rather than through or to a wholesaler,
16 your company won't be able to rely on the
17 wholesaler thresholds as its last line of
18 defense, right?

19 MR. BARKER: Object to form.

20 THE WITNESS: That is what I
21 wrote.

22 BY MR. JANUSH:

23 Q. Thank you.

24 Also, at the bottom of the

1 page, you addressed, "If Stefan talks to
2 you about CSC" -- is that controlled
3 substance compliance?

4 A. Yes.

5 Q. -- "please reinforce SOM. I
6 don't think any of the leaders understand
7 or know the work JOM customer service and
8 CSC do."

9 Do you see that?

10 A. Yes, I do.

11 Q. What was causing you to say
12 this, to write this, at this point this
13 time on May 6, 2014?

14 A. Because I reported in to
15 Janssen Supply Chain which was separate
16 than JOM, and reported in through
17 Noramco. And I wanted his support should
18 we need resources or capital to change
19 our program.

20 (Document marked for
21 identification as Exhibit
22 Dempsey-12.)

23 BY MR. JANUSH:

24 Q. I'm going to hand you what's

1 been marked as Dempsey Exhibit 12.

2 This is a document dated
3 August 21, 2017. It's -- the subject is
4 "Review of suspicious order monitoring
5 questionnaires." It looks like the
6 participants in this review meeting were
7 you and Belinda Corum. Who is Belinda
8 Corum?

9 A. She is the control substance
10 specialist located at the Kentucky
11 distribution center.

12 Q. Okay. And this appears to
13 be a memo addressing the following
14 company files that were reviewed, and I
15 counted 19 different files that had been
16 reviewed to determine the date of the
17 most recent questionnaire that had been
18 completed and whether the customer was an
19 active customer of JOM Pharmaceutical
20 Services, Inc.

21 Do I have that right?

22 A. Yes. We were doing a review
23 of the questionnaires that we had on land
24 and if the customer were still active.

1 Q. Okay. And I just want to
2 draw your attention to Cardinal. Date of
3 most recent questionnaire was August 17,
4 2012.

5 Do you see that?

6 A. Yes.

7 Q. And this -- this is five
8 years later that you're doing your review
9 in August of 2017; is that right?

10 A. We had been looking at these
11 questionnaires throughout the year. This
12 was a formal, let's review all of them
13 and assess where we are with these.

14 So, you know, this was -- we
15 had -- these questionnaires were looked
16 at before, previously. But we were doing
17 an annual -- this was our first, let's do
18 an annual review, what does it have and
19 what do they say. So yes for Cardinal.
20 We knew on file that we had a form letter
21 in 2015, and they did fill out a
22 questionnaire in 2012.

23 Q. So Ms. Dempsey, all I was
24 addressing was that it was August 2017,

1 and you were noting that the date of
2 their most recent questionnaire was
3 August 2012, right? Yes or no?

4 A. I wrote in this review that
5 we looked at the questionnaires, and that
6 was the date.

7 Q. Okay. The --

8 A. But you're implying that I
9 never saw these questionnaires, but I
10 did.

11 Q. No, I'm not I am supplying
12 anything. That's not -- that's actually
13 not what I was seeking to imply.

14 A. Okay.

15 Q. I'm seeking to imply the
16 following.

17 I'm actually not seeking to
18 imply anything. I'm going to have you
19 address it and you testify.

20 Date of most recent
21 questionnaire was August 12, 2017.

22 That only reflects -- that
23 reflects the questionnaire that you sent,
24 the date that you sent a questionnaire.

1 The fact is that Cardinal
2 didn't ever complete that questionnaire,
3 but responded with a form letter to the
4 2015 questionnaire request; isn't that
5 right? Look under actions?

6 A. No. The first --

7 MS. BOODY: Object to form.

8 THE WITNESS: The first
9 column is the date of the
10 questionnaire we have on file. So
11 we had a questionnaire completed
12 by Cardinal in 2012.

13 BY MR. JANUSH:

14 Q. Was it -- was the 2012
15 questionnaire your four-question
16 questionnaire?

17 A. Yes, it is.

18 Q. Okay. And so the later
19 questionnaire that was sent out in '15
20 was the one where you had Buzzeo's
21 guidance and you upped it to a multi-page
22 questionnaire; is that right?

23 A. Yes.

24 Q. Okay. And so Cardinal

1 responded to the four question
2 questionnaire in 2012; is that your
3 testimony?

4 A. Yes.

5 Q. But when you sent the more
6 robust multi-page questionnaire in 2015,
7 is it right that Cardinal responded with
8 a form letter to your 2015 questionnaire?

9 A. They did provide us a form
10 letter in 2015, and did not complete the
11 questionnaire.

12 Q. Okay. And let's go down to
13 McKesson. McKesson, coincidentally,
14 responded to your 2012 questionnaire on
15 the very same date, on August 17, 2012;
16 is that right?

17 A. That was the four-question
18 questionnaire.

19 Q. And McKesson responded on
20 the very same day as Cardinal; is that
21 right?

22 A. That is the date that's on
23 the questionnaire.

24 Q. Okay. And Frank W. Kerr

1 responded on August 17, 2012, the same
2 date as Cardinal; is that right?

3 MS. BOODY: Object to form.

4 THE WITNESS: That -- that
5 is the date that was on the
6 questionnaire in the folder, in
7 the file.

8 BY MR. JANUSH:

9 Q. In other words, it might not
10 be the date that the response was
11 received; is that right?

12 A. That was the date we
13 received it.

14 Q. Okay. And when we look at
15 McKesson, "Actions, responded with a form
16 letter to the 2015 questionnaire
17 requests."

18 Did I read that right?

19 A. Responded with a form
20 letter -- yes. Yes you did.

21 Q. So McKesson and Cardinal
22 both did not fill out JOM's questionnaire
23 concerning suspicious order monitoring
24 systems; is that right?

1 A. Yes.

2 Q. How did you feel about that?

3 MR. BARKER: Object to form.

4 THE WITNESS: We had the

5 original questionnaire on file.

6 So technically, we understood they

7 had a program. And we did request

8 the new questionnaire. But the

9 2012 questionnaire answered our

10 question, did you have a program

11 in place, and were our products

12 covered.

13 BY MR. JANUSH:

14 Q. If it answered -- how sure
15 are you about that, that it answered your
16 question, if you had a program in place
17 and were our products covered?

18 A. They described their -- in
19 2012?

20 Q. Yeah.

21 A. I believe both of these
22 questionnaires had a high-level summary
23 of their programs.

24 Q. I'm just waiting to see if

1 you're done.

2 A. Oh, I'm done.

3 Q. If your four-question
4 questionnaire was good enough, why did
5 you draft a multi-page questionnaire in
6 2015?

7 MR. BARKER: Object to form.

8 THE WITNESS: Throughout the
9 years, we identified enhancements
10 to make our program more robust so
11 we could provide DEA what they
12 wanted to see. They never asked
13 for questionnaires. We reviewed
14 our program with them. When
15 Cardinal and McKesson did not fill
16 out the questionnaire, I did
17 follow up. And I did understand
18 that because of the current --
19 they were being investigated, and
20 they did not complete
21 questionnaires at that time. And
22 that is why we only got the form.

23 BY MR. JANUSH:

24 Q. So --

1 A. So within -- so, like, I
2 just wanted to have it on record that we
3 continued to engage with Cardinal and
4 McKesson in regards to this
5 questionnaire, and we did follow-up. I
6 met with my two counterparts at these two
7 locations to ask why they never completed
8 the questionnaires. And I was informed
9 it was because they were -- there were
10 legal reasons. And they both have
11 invited us to come and see their
12 programs.

13 But they did not -- at this
14 time in 2015, and -- '15 did they
15 complete our questionnaire.

16 (Document marked for
17 identification as Exhibit
18 Dempsey-13.)

19 BY MR. JANUSH:

20 Q. Okay. I'm going to hand you
21 what's been marked as Dempsey Exhibit 13.
22 I believe this is an example of your
23 questionnaire in March of 2015. And I'm
24 really only entering it into the record

1 as an exemplar. So first of all, is this
2 the 2015 questionnaire that Cardinal and
3 McKesson did not complete?

4 MR. BARKER: Object to form.

5 THE WITNESS: This is dated
6 March 2015. And it most likely
7 was.

8 BY MR. JANUSH:

9 Q. Okay. And the questionnaire
10 addressed issues like general issues
11 about the company, the DEA registration
12 number, company ownership. In Section 3,
13 prior history and associations concerning
14 whether the registrant had ever had a DEA
15 registration denied, suspended, or
16 revoked.

17 Do you see that?

18 A. Yes, I do.

19 Q. And other examples of items
20 are -- of information that you're seeking
21 is business information, is the
22 company -- is the company affiliated with
23 any business that handles controlled
24 substances through internet websites.

1 That's at Number 28, right?

2 A. Mm-hmm.

3 Q. Okay. And then at Section
4 5, you are addressing, "Does the company
5 have a suspicious order monitoring
6 program? Please describe your program.
7 Is there a standard operating procedure
8 that describes the suspicious order
9 monitoring system?" And then at Number
10 34, you are addressing very specific
11 drugs that Janssen or JOM and -- I should
12 say that Janssen and JOM sell.

13 You ask, "Are Nucynta,
14 Nucynta ER, Duragesic, Concerta, Tylox,
15 Tylenol with codeine, Ultracet, and
16 Ultram covered in your SOM program? If
17 so, provide threshold limits if
18 applicable."

19 Did I read that right?

20 A. Yes.

21 Q. What's the reason for
22 seeking information as to whether your
23 company's drugs are included within a
24 distributor's suspicious order monitoring

1 program?

2 A. It's part of our due
3 diligence with our customers. We want to
4 make sure, A, they have a suspicious
5 order monitoring program; and, B, that
6 our controlled substances are included in
7 that program.

8 Q. Why is that important?

9 A. We want to make sure that
10 they are doing their due diligence in
11 regard to C.F.R. 1301.74(b) about
12 operating a system to monitor orders for
13 unusual size, quantity, frequency, and
14 patterns.

15 Q. It's important for you to
16 know the answers to these questions
17 because you are selling to these
18 distributors your opioid products, right?

19 A. It is important for us to
20 meet our requirement to operate an order
21 monitoring program where we know our
22 customers and that they are doing their
23 due diligence in monitoring those
24 products as well. All controlled

1 substances.

2 MS. BOODY: Could I just see
3 a copy of Exhibits 12 and 13? I
4 don't think you have the Bates
5 number on the record.

6 Thank you.

7 MR. JANUSH: For the record,
8 the Bates number of Exhibit 13 is
9 JAN-MS-02964406.

10 And Exhibit 12 is
11 JAN-MS-02963380.

12 (Document marked for
13 identification as Exhibit
14 Dempsey-14.)

15 BY MR. JANUSH:

16 Q. I'm going to hand you what's
17 been marked as Dempsey Exhibit 14.

18 And earlier I -- I addressed
19 how you drafted your questionnaire. And
20 this just confirms for the record that
21 you wrote to Brian Strehlke, Michael
22 Levitt, Guy Bacco and Art Dysart, "I took
23 the Buzzee questionnaire and blended our
24 questions. Could you all review and let

1 me know your thoughts by this Wednesday?
2 I have a meeting with trade to review.
3 Would like to get this to ABC, Cardinal
4 and McKesson before our May visits.
5 Thanks."

6 Did I read that accurately?

7 A. Yes, you did.

8 Q. Okay. Why was it important
9 to you to get this to ABC,
10 AmerisourceBergen, Cardinal, and McKesson
11 before your May visits?

12 A. We had intended to have --
13 to set up meetings. I was going to work
14 with trade in order to meet with the
15 wholesalers to review our new
16 questionnaire.

17 Q. Did that meeting happen?

18 A. The meeting with trade did
19 happen.

20 Q. Did the meeting with
21 McKesson happen?

22 A. No.

23 Q. Why not?

24 A. They were not available to

1 meet.

2 Q. Do you know why?

3 A. No.

4 Q. Did the meeting with
5 Cardinal happen?

6 A. No.

7 Q. Do you know why?

8 A. No. The meeting with ABC
9 did occur.

10 (Document marked for
11 identification as Exhibit
12 Dempsey-15.)

13 BY MR. JANUSH:

14 Q. I'm going to hand you what's
15 been marked as Exhibit 15. And this is
16 Bates Number JAN-MS-02966153.

17 And I'm going to draw your
18 attention to the third page. There's an
19 attachment or a forward from the DEA to
20 Michele Dempsey, subject, McKesson agrees
21 to pay record \$150 million settlement for
22 failure to report suspicious orders of
23 pharmaceutical drugs.

24 Do you see that?

1 A. Yes, I do.

2 Q. And you, on the next day, on
3 January 18th, a day after receiving this,
4 forwarded this on to Frank Mashett and
5 asked if Frank can confirm whether the
6 Ohio distribution center listed below is
7 the location we ship schedules and what
8 precautions we should take in order to
9 ensure we don't ship to a location that
10 no longer is allowed to have CS, right?

11 A. Yes.

12 Q. For the record, can you
13 speak up?

14 A. Yes.

15 Q. Okay. And who is Frank
16 Mashett?

17 A. He was in the trade.

18 Q. So does that mean that he's
19 involved in sales?

20 A. No. He managed the
21 relationship with the wholesalers.

22 Q. Okay. Did he manage the
23 relationship with McKesson at this time,
24 in 2017?

1 A. No. As he was to remind me
2 that Phil West was the director for
3 McKesson.

4 Q. Sorry, I see that right
5 above.

6 So Frank responded by
7 letting you know Phil West is the trade
8 account director for McKesson and SeWha
9 Park is the JOM planner. The two of them
10 would be best to address my questions you
11 have related to this issue involving
12 McKesson.

13 And you respond, "Can you
14 please advise? Thanks." Right?

15 And you're writing to Phil
16 West and SeWha Park?

17 A. Yes.

18 Q. Okay. And the answer that
19 you got from Phil West was, "Hi, Michele.
20 This has been an on" -- "this has been
21 ongoing litigation and McKesson has
22 contingency plans in place to leverage
23 their distribution center network over 30
24 sites to continue continuity of product.

1 SeWha is actively engaged with McKesson."

2 Do you see that?

3 A. Yes.

4 Q. That didn't exactly answer
5 your question, did it?

6 MR. BARKER: Object to form.

7 THE WITNESS: It did not
8 answer my question about what was
9 going into Ohio.

10 BY MR. JANUSH:

11 Q. Okay. And SeWha then wrote
12 back, "Hello, Michele. JOM ships
13 scheduled products and controlled
14 substances to McKesson's RDC/regional
15 distribution center, Olive Branch, and
16 RDC distributes down to their forwarding
17 distribution centers. So from JOM
18 perspective, we do not sell/ship
19 scheduled products/controlled substances
20 direct to McKesson forwarding
21 distribution centers. We will review
22 this article with McKesson team to
23 receive any information and actions that
24 are required on our side."

1 Did I read that right?

2 A. Yes.

3 Q. And you responded and I'm
4 not going to read your whole response,
5 but I'm going to read the part that I
6 want to focus most on. And you can see
7 where I'm going. I'm drawing it out for
8 you on the Elmo.

9 You wrote, "Hello, SeWha."
10 In your second paragraph, you said, "I do
11 have one more question. Glad to see
12 there are contingency plans, but since
13 McKesson failed to fill out our
14 suspicious order monitoring
15 questionnaire, choosing only to send us a
16 blanket letter saying they have a
17 suspicious order monitoring program, can
18 we confirm somehow that Concerta, Tylenol
19 with codeine, Ultram, or Duragesic were
20 not involved? Our questionnaire, if they
21 completed it, would have told us if our
22 products were in their SOM program."

23 Did I read that correctly?

24 A. You did read that correctly.

1 Q. So do you know where I'm
2 going right now?

3 MR. BARKER: Object to form.
4 BY MR. JANUSH:

5 Q. I'm going back to your
6 earlier testimony where you addressed
7 that four-question questionnaire and said
8 you would have felt comfortable because
9 you would have known from that
10 questionnaire that your products were
11 included in their program. Do you
12 remember testifying in that way?

13 A. Yes. And I believe the
14 second question of that four-question
15 questionnaire asked them are our products
16 included.

17 Q. And here you are addressing
18 a worry on January 18, 2017, not that
19 long ago, that --

20 THE VIDEOGRAPHER: Lower
21 that page, because it's not
22 projecting.

23 MR. JANUSH: Thank you.

24 BY MR. JANUSH:

1 Q. You're addressing a worry
2 that because McKesson "failed to fill out
3 our SOM questionnaire, choosing only to
4 send us a blanket letter saying they have
5 a suspicious order monitoring program,
6 can we somehow confirm that Concerta,
7 Tylenol with codeine, Ultram or Duragesic
8 were not involved? Our questionnaire, if
9 they completed it, would have told us if
10 our products were in their SOM program."

11 Now read it a second time.
12 Do you see it?

13 A. Yes, I do see it.

14 Q. This would be a superfluous
15 or unnecessary question if you truly had
16 a four-question questionnaire in your
17 pocket from McKesson that answered this
18 issue, wouldn't it?

19 MR. BARKER: Object to form.

20 THE WITNESS: We did have
21 the four-question answer from
22 McKesson. What we didn't have is
23 the eight-page detailed one that
24 went into length about their

1 algorithm and thresholds.

2 BY MR. JANUSH:

3 Q. Miss, you are not -- you're
4 not -- Ms. Dempsey, you are not
5 addressing algorithms and thresholds
6 here.

7 You are addressing whether
8 you can confirm that these specifically
9 named products, Concerta, Tylenol with
10 codeine, Ultram or Duragesic were
11 involved in the problem, and that your
12 questionnaire, if completed, would have
13 told you if your products were included
14 in their program, their SOM program.

15 Isn't that what this is
16 addressing?

17 MR. BARKER: Object to form.

18 THE WITNESS: This was about
19 the new questionnaire that we
20 would have had on file, yes.

21 BY MR. JANUSH:

22 Q. And it was addressing
23 whether your products were included in
24 their SOM program, correct?

1 A. Yes.

2 Q. So if your four-question
3 questionnaire gave you such comfort, why
4 in the world would you have sent this
5 e-mail?

6 A. Because we wanted to have
7 the longer questionnaire on file, which
8 would go into more detail about their
9 program, beyond the high-level summary
10 that we had received in the past.

11 Q. But again, in your e-mail,
12 you're not addressing high-level issues,
13 are you? You're addressing just wanting
14 to confirm if these named products sold
15 by Janssen and JOM were involved in their
16 SOM program, correct?

17 A. Yes.

18 (Document marked for
19 identification as Exhibit
20 Dempsey-16.)

21 BY MR. JANUSH:

22 Q. I'm going to hand you what
23 I'm going to mark as Exhibit 16. Now, at
24 this e-mail, we're going back in time to

1 September of 2012. On the second page --
2 and this e-mail is Bates-stamped
3 JAN-MS-02963719.

4 And here -- I'm addressing
5 Steve Noetzel's e-mail. And he is
6 writing -- and you're cc'd, by the way.
7 I'm circling so you can find your name on
8 the Elmo.

9 A. I just want to review the
10 whole document, if you don't mind.

11 Q. Sure.

12 A. Thank you.

13 Q. So I'm on the second page.

14 I'm looking at the bottom of the page.
15 Steve Noetzel is writing to a host of
16 individuals at Johnson & Johnson,
17 Janssen, it looks like Noramco as well.
18 And is writing, "All, the DEA has
19 announced an immediate suspension of
20 Walgreens' license to ship Schedule C-II
21 through V products from their Jupiter,
22 Florida distribution center. Tim and I
23 have already spoken about this with our
24 respective accounts, and here's the

1 takeaway. Walgreens only warehouses a
2 select few C-II through IV products. The
3 rest are sold direct to store from the
4 Cardinal distribution centers in
5 Wheeling, West Virginia and Madison,
6 Mississippi. Cardinal will now supply
7 all C-II to IV --

8 A. To V.

9 Q. Sorry, to V.

10 A. It says to V.

11 Q. My eyes are playing tricks
12 on me this late in the day.

13 A. That's okay.

14 Q. -- "products to Walgreens
15 stores via the direct-to-store method as
16 they do all other Janssen products.
17 There should be no interruption of supply
18 of our products to any Walgreens store.
19 This should be business as usual for all
20 Walgreens stores. We will keep you
21 posted as this progresses."

22 You wrote back, "I
23 understand trade's standpoint of ensuring
24 continuity of supply for our products.

1 However, here is more details."

2 And you provided the DEA
3 publication of the suspension order, a
4 link to it, didn't you?

5 A. There is a link to -- from
6 the DEA website.

7 Q. And you wrote, "Should we
8 collect 2009 to 2011 data on our
9 controlled substances products at the
10 Walgreens listed to see if there is a
11 similar trend?" Right?

12 A. Yes.

13 Q. And following that -- well,
14 let's pause there.

15 You've said a lot throughout
16 the day that you didn't ship directly to
17 Walgreens or the individual store level,
18 right?

19 A. Yes.

20 Q. And that it wasn't your
21 responsibility to know your customers'
22 customer, right?

23 A. At this time, DEA did not
24 ask us to know beyond our customer.

1 Q. And yet you were worried
2 enough after reading the suspension order
3 to seek to collect data from 2009 to 2011
4 on your controlled substance products at
5 this Walgreens site to see if there is a
6 similar trend, right?

7 MR. BARKER: Object to form.

8 THE WITNESS: I wanted them
9 to use what data they had
10 available to see if we could see
11 how much was going into this area
12 in Florida.

13 BY MR. JANUSH:

14 Q. And data was reviewed. We
15 can see at the bottom of Page 1, Greg
16 Wolski writes back. "We reviewed
17 controlled substances sales of JOM
18 products from Cardinal to the location we
19 believe to be Walgreens Jupiter
20 distribution center. We cannot
21 100 percent confirm this is the data for
22 the location, since it is blinded, but we
23 believe that it is. We trended the sales
24 for 2011 and 2012 year to date, and

1 found:"

2 And thereafter they
3 address -- Greg Wolski addresses, over
4 this time period, that the Jupiter
5 distribution center stocked five
6 strengths of Duragesic, four strengths of
7 Concerta, and one strength of Nucynta.

8 A. Yeah, so they had --

9 Q. Right?

10 A. They had the data for the
11 Cardinal Jupiter location. Using their
12 867 data, they were able to identify
13 that.

14 Q. And even down to, at the
15 fourth line, the language, "The most
16 heavily purchased product was Nucynta IR
17 50 milligrams, which had average
18 purchases/sales of 324 bottles per week."

19 Do you see that?

20 A. Yes, I do.

21 Q. Okay. And at the top of
22 this e-mail, you then address the notion
23 that, "We should be doing this," and by
24 "this" I think you mean this kind of an

1 intense review, "not just when DEA shuts
2 down Walgreens... Mike and I fear that
3 JOM is going to reduce head count and
4 there will not be anyone left to do this
5 kind of analysis. These are the key
6 products we should be constantly
7 monitoring, but the current process of
8 collecting data is time consuming. Took
9 Greg all week."

10 Do you see that?

11 A. Yes, I do.

12 Q. The process to collect this
13 data was time consuming because your
14 group wasn't working with an outside
15 vendor to know your customers' customer,
16 was it?

17 MR. BARKER: Object to form.

18 THE WITNESS: The reason it
19 took a lot of time was it was
20 blinded and we had to look at this
21 data for this one DC location.
22 And as I explained before, DEA
23 never asked us for this
24 information. We were doing this

1 out of our own review.

2 BY MR. JANUSH:

3 Q. But as we've addressed
4 earlier today, blinded data can be
5 unblinded by outside third-party vendors
6 and by chargeback data by 852, by 867
7 data, correct?

8 MR. BARKER: Object to form.

9 THE WITNESS: That came out
10 in 2017 and 2018. But back then,
11 in 2012, DEA did not ask for that
12 information. They did not expect
13 the manufacturers to be reviewing
14 that information.

15 BY MR. JANUSH:

16 Q. When you say that came out
17 in 2017, you're only referring to the
18 "that" as being the DEA --

19 A. The downstream data.

20 Q. The DE -- let me finish my
21 question.

22 You are referring to the
23 DEA's determination in a case against
24 Mallinckrodt; is that right?

1 A. Yes.

2 Q. You're not referring to the
3 notion that the technology didn't exist
4 in 2012 to unblind data, right?

5 MR. BARKER: Object to form.

6 THE WITNESS: In 2012, I did
7 not know that there was a
8 technology to unblind the data or
9 that we needed to unblind the data
10 because DEA never asked for that
11 data.

12 MR. BARKER: Are you sure
13 you don't want to use the copy
14 with your notes on it? You can
15 just hand it right over.

16 (Document marked for
17 identification as Exhibit
18 Dempsey-17.)

19 BY MR. JANUSH:

20 Q. Please find Exhibit 17.

21 This is Bates stamped JAN-MS-03115514.

22 And this is also attaching a
23 compliance PowerPoint that's Bates
24 stamped JAN-MS-03115516.

1 So I'm going to focus your
2 attention to the bottom of Page 1 where
3 Steve Noetzel is writing to a big group
4 and cc'ing you.

5 A. Mm-hmm.

6 Q. And he's addressing, "All, I
7 heard back from Cardinal again last night
8 and wanted to provide you all with an
9 update.

10 "The DEA has not yet
11 suspended Walgreens license for
12 controlled products from their
13 Perrysburg, Ohio, distribution center.
14 Walgreens has decided, however, to
15 voluntarily discontinue shipping Class II
16 through V products from this location for
17 the time being. As of now they are
18 depleting all inventory and receiving no
19 replenishment for controlled products
20 until further notice.

21 Walgreens will begin
22 shipping Class III to V products to their
23 stores serviced out of Perrysburg from
24 another Walgreens distribution center.

1 "Class II products, on the
2 other hand, will now be shipped to most
3 of these stores from Cardinal.

4 "As of this morning,
5 Cardinal will be able to ship product to
6 95 percent of the Walgreens stores
7 serviced out of the Perrysburg facility."

8 Did I read that right?

9 A. You read what the e-mail
10 states.

11 Q. Okay. And Steve is
12 addressing further in the e-mail,
13 "Finally, I want to alleviate any
14 concerns that the situation at the
15 Perrysburg facility is not a result of
16 any DEA concerns with any Janssen
17 products."

18 Did that -- did I read that
19 correctly as well?

20 A. Yes.

21 Q. Okay. And the e-mail
22 attaches a PowerPoint addressing the
23 current DEA external environment in 2012.
24 And it's on Janssen -- I'm going to try

1 and shrink this. It's on Janssen paper,
2 with Janssen's emblem.

3 Did you create this
4 PowerPoint?

5 A. Yes.

6 Q. Okay. And it's 2012. And
7 you are addressing "intense scrutiny
8 of" -- "of industry.

9 "Manufacturers, formulators
10 being called to Washington to explain
11 suspicious order monitoring programs."

12 Who were you referring to
13 when you drafted this PowerPoint slide
14 that had been called to Washington to
15 explain their SOM programs?

16 A. From my Noramco due
17 diligence and know your customer, I know
18 that some of the formulators, as I
19 mentioned before KVK, was asked to go
20 down to Washington to explain their
21 suspicious order monitoring programs.

22 Q. Okay. But you -- you listed
23 manufacturers plural and formulators
24 plural. Who beyond KVK were you

1 referring to?

2 A. I can only remember KVK at
3 this time. I do know at conferences, DEA
4 spoke in plural. Manufacturers were
5 being called to Washington.

6 We were never called down.

7 Q. And if you turn to Slide 3,
8 did you draft this or did the -- did you
9 get this from a DEA slide, this
10 controlled substance compliance pyramid?

11 A. This was part of a DEA site
12 training that was developed at our Athens
13 facility. So a specialist put this
14 together.

15 Q. Okay. And when you say a
16 specialist, is that a --

17 A. A DEA compliance specialist
18 at the API manufacturing location, based
19 on what we had heard from previous
20 conferences.

21 Q. Okay. And -- and when you
22 say a DEA compliance specialist, you're
23 referring to a JOM employee?

24 A. A Noramco.

1 Q. A Noramco employee.

2 A. Right.

3 Q. Okay. So you had a Noramco
4 employee putting on a presentation on
5 Janssen and Johnson & Johnson letterhead
6 for which company's employees?

7 MR. BARKER: Object to form.

8 THE WITNESS: I pulled a
9 compliance deck that we usually
10 had from previous onsite training.
11 I pulled relevant slides that
12 somebody else developed the
13 content, into this overall
14 compliance slide deck for 2012.

15 BY MR. JANUSH:

16 Q. And -- and what company did
17 the employees work for who were receiving
18 this discussion?

19 MR. BARKER: Object to form.

20 THE WITNESS: I forwarded --
21 I was forwarding this to the
22 quality manager at JOM for
23 consideration of inclusion in
24 their routine DEA compliance

1 training.

2 BY MR. JANUSH:

3 Q. Okay.

4 A. She owned the training
5 program.

6 Q. And listed as a major
7 violation, wilful nonconformance with
8 federal regulations. No internal DEA
9 compliance processes in place to...

10 And we have things like
11 "detect and prevent diversion"; is that
12 right?

13 A. Yes.

14 Q. And, "submit DEA reports."
15 That's listed as well, right?

16 A. Mm-hmm.

17 Q. And, "identify and report
18 suspicious orders" is also listed, right?

19 A. Yes.

20 Q. And "train employees" is
21 also listed as a major violation; is that
22 right?

23 A. Yes.

24 Q. What's that regarding, train

1 employees?

2 A. Make sure that those that
3 are handling controlled substances know
4 how the regulations apply to their
5 activities.

6 Q. Okay. And control
7 distribution of controlled substance is
8 listed as a major -- an area for major
9 violation; is that right?

10 A. Well, it's listed as if you
11 do not demonstrate anything and having no
12 process in place to control the
13 distribution, you will potentially get
14 a -- a violation with the DEA.

15 Q. Now on to the next page you
16 address serious violations, right?

17 A. The next level down, yes.

18 Q. And at serious violations
19 you address "failure to implement
20 corrective actions that cause deviations
21 from federal regulations or internal DEA
22 compliance processes."

23 Did I read that correctly?

24 A. Yes, you did.

1 Q. And the second arrow you
2 address "consequence of deviations could
3 cause reporting errors or allow diversion
4 to go undetected."

5 Did I read that correctly?

6 A. Yes, you did.

7 Q. Would it be a serious
8 violation if you had a suspicious order
9 monitoring system that shuts off in the
10 afternoon and would permit orders that
11 come in after 3:45 p.m. to potentially go
12 out unchecked?

13 MR. BARKER: Object to form.

14 THE WITNESS: All orders of
15 controlled substances are placed
16 on hold until they've gone through
17 the algorithm.

18 MR. JANUSH: Move to strike,
19 nonresponsive.

20 BY MR. JANUSH:

21 Q. I asked you would it be a
22 serious violation if you had a suspicious
23 order monitoring system that shuts off in
24 the afternoon and would permit orders

1 that come in after 3:45 p.m. to
2 potentially go out unchecked?

3 MR. BARKER: Object to form.

4 BY MR. JANUSH:

5 Q. You can answer.

6 A. If a suspicious order was
7 released, it did not fall -- go through
8 the monitoring program, it could be a
9 violation.

10 Q. A serious violation, right?

11 A. Yes, according to this, a
12 serious violation.

13 Q. Before we put that exhibit
14 away, let's go back to 17 just for a
15 moment.

16 I went through the
17 compliance slides very briefly with you
18 just now that you attached to this
19 e-mail. And I'm going to circle --
20 that's that document that I circled. You
21 can look at the screen.

22 Is that right?

23 A. Yeah. Yeah.

24 Q. Okay. And -- and you wrote

1 to Maryann Gribbin, "I asked Mike to
2 update the JOM DEA training. We both
3 agree more focus on suspicious order
4 monitoring needs to be added.

5 "Next week at HDMA should be
6 interesting. Hope you don't mind my
7 e-mail is just to you, not to Steve.
8 Being in compliance, I know you get it.
9 For Steve it is about the sale. Ha-ha!"

10 Do you see that?

11 A. Yes, I do.

12 Q. Steve Noetzel, he's the
13 trade guy, right?

14 A. He managed the relationship
15 with the wholesaler.

16 Q. So you're writing an e-mail
17 that cut out Steve to not offend him and
18 to address to Maryann the importance of
19 JOM DEA training and with a greater focus
20 on suspicious order monitoring; is that
21 right?

22 A. As in charge of the quality
23 assurance compliance at JOM, she would
24 manage the training program, and so I

1 directly sent this to her asking for her
2 inclusion in the routine training for DEA
3 compliance. I --

4 Q. But you also -- go ahead.

5 A. Now I lost my train of
6 thought. Sorry.

7 Q. Sorry. I apologize.

8 A. That's okay.

9 Q. I was just going to address,
10 but you also wrote with purpose, didn't
11 you, when writing, "Hope you don't mind
12 my e-mail is just to you, not to Steve.
13 Being in compliance, I know you get it.
14 For Steve, it is all about the sale,
15 ha-ha."

16 MR. BARKER: Object to form.
17 Is there a question?

18 BY MR. JANUSH:

19 Q. You wrote that, right?

20 A. I wrote that, yes.

21 (Document marked for
22 identification as Exhibit
23 Dempsey-18.)

24 BY MR. JANUSH:

1 Q. Ms. Dempsey, I'm handing you
2 what I've marked as Dempsey-18.

3 This document concerned
4 language regarding esketamine, right?

5 A. Yes.

6 Q. What is esketamine?

7 A. It is a new product that
8 Janssen has developed, and is in clinical
9 trials and awaiting approval from FDA.

10 Q. What kind of product is it?

11 A. It is psychotropic
12 non-narcotic for depression.

13 Q. Okay. And isn't it true
14 that you admitted in this e-mail that
15 because Janssen's brand volume is very
16 low, we do not have experience around
17 suspicious order monitoring?

18 MR. BARKER: Object to form.

19 THE WITNESS: Let me read
20 what he wrote.

21 Okay. So this is in regards
22 to the distribution pattern that
23 is being proposed for esketamine
24 where it's going to the healthcare

1 provider. And so I was saying
2 that our current suspicious order
3 monitoring program, which only
4 goes to the wholesaler, we don't
5 have that experience delivering
6 directly to a doctor's office.

7 The -- esketamine will be
8 administered under the supervision
9 of a healthcare provider.

10 BY MR. JANUSH:

11 Q. You were being asked, "Hi,
12 Michele. We are finalizing a Q&A for J&J
13 Pharma analyst day on May 17. Are you
14 okay with the copy below re esketamine
15 and potential abuse as well as potential
16 for REMS program?" That is a risk
17 evaluation mitigation strategy program,
18 right?

19 A. Yes.

20 Q. "I believe you have seen
21 this previously."

22 A. Yes.

23 Q. "Thanks, Greg."

24 And he -- you write in your

1 first response, "Number one, I don't
2 consider what we have done for Concerta
3 and Duragesic can be called deep
4 experience."

5 That's responding to a
6 general question about, are you okay with
7 the copy below re esketamine and
8 potential abuse as well as potential for
9 REMS program, isn't it?

10 A. So I was questioning the
11 word "deep," because that implies that we
12 had multiple products in large volumes.
13 So I was saying our experience in
14 manufacturing, in commercialization, I
15 would not call that a deep experience,
16 and that when we launched Concerta in
17 2000 -- and I -- excuse me, I don't
18 remember when Duragesic launched, those
19 requirements back then are not as -- the
20 requirements are different in 2017, as
21 when we launched our other controlled
22 substances --

23 Q. Are you --

24 A. -- in regards to -- there's

1 been more enhancements to our suspicious
2 order monitoring and the requirements for
3 our current distribution.

4 Q. The answer that you just
5 gave implies that you are completely
6 unaware that REMS programs were initiated
7 for Duragesic after its launch, in the
8 years after its launch?

9 MR. BARKER: Objection.

10 BY MR. JANUSH:

11 Q. Were you aware of that?

12 MR. BARKER: Object to form.

13 BY MR. JANUSH:

14 Q. In other words, you're
15 analyzing the environment when Duragesic
16 originally launched. But in between that
17 year that Duragesic launched in the 1990s
18 and the present date, a lot has happened
19 concerning risk evaluation and mitigation
20 strategies related to Duragesic; isn't
21 that true?

22 MR. BARKER: Object to form.

23 THE WITNESS: In my realm at
24 this point, I was not involved in

1 the REMS. I'm not medical
2 affairs. So I would not know what
3 was exactly done in regard to
4 Duragesic REMS.

5 BY MR. JANUSH:

6 Q. But -- so you're giving a
7 wrong -- you're giving a wrong answer
8 here, aren't you, saying -- by saying --
9 without knowing, by saying you wouldn't
10 consider what we have done for Concerta
11 and Duragesic can be called deep
12 experience. "The environment has changed
13 substantially in regards to abuse and the
14 requirements for due diligence on the
15 pharmaceutical companies since we
16 launched those products, and because our
17 brand volume is very low, we do not have
18 experience around suspicious order
19 monitoring."

20 The answer that you gave
21 failed to take into account Janssen's
22 experience attempting to address --
23 address risk evaluation and mitigation
24 strategies concerning Duragesic in the

1 years after its launch, didn't it?

2 MR. BARKER: Object to form.

3 THE WITNESS: I can't speak
4 to REMS. As I said, I'm in the
5 DEA compliance base, which is DEA,
6 not FDA. So I was not aware of
7 what was done with Duragesic in
8 regards to REMS.

9 BY MR. JANUSH:

10 Q. So why didn't you say that
11 in your answer?

12 A. I was reading here what they
13 -- the summary. They -- they weren't
14 even talking about REMS in this
15 paragraph. Well, the risk mitigation
16 plans. They mentioned Janssen has deep
17 experience.

18 So based on my limited
19 knowledge of manufacturing and the DEA
20 compliance, I wouldn't say that we had
21 deep recent experience. And that's what
22 I was trying to say up above.

23 Q. Do you understand -- do you
24 understand that Duragesic had been on the

1 market for over 20 years when you wrote
2 this responsive e-mail?

3 A. I knew it had been for a
4 long time. Not the 20 years.

5 Q. And you're addressing a
6 20-year fentanyl product that had been
7 being sold -- that had been sold by
8 Janssen, each of those 20-plus years
9 had -- was associated with not much
10 experience around suspicious order
11 monitoring, are you not?

12 MR. BARKER: Objection.
13 Object to form.

14 MR. JANUSH: I'll ask it
15 differently.

16 BY MR. JANUSH:

17 Q. You wrote, "Since we
18 launched those product" -- "the
19 environment has changed substantially in
20 regards to abuse and the requirements for
21 due diligence on the pharmaceutical
22 company since we launched those products,
23 and because our brand volume is very low,
24 we do not have experience around

1 suspicious order monitoring."

2 And that was in relation to
3 Concerta and Duragesic, was it not, those
4 words?

5 MR. BARKER: Object to form.

6 THE WITNESS: It was for
7 Concerta and Duragesic, in 2017,
8 the number of orders that we were
9 handling.

10 BY MR. JANUSH:

11 Q. But you're addressing in
12 2017 a lookback -- you're using the word,
13 "Since we launched those products and
14 because our brand volume is very low, we
15 do not have experience around suspicious
16 order monitoring."

17 Your words are not just
18 limited to 2017, are they?

19 MR. BARKER: Object to form.

20 THE WITNESS: I was
21 comparing our current number of
22 orders for those products to
23 when -- so this -- we were getting
24 ready to launch a new product.

1 And I was trying to relay that the
2 environment is a lot different
3 than when we launched Concerta,
4 which is the other non-narcotic as
5 well as Duragesic, which you
6 reminded me was over 20 years old.

7 (Document marked for
8 identification as Exhibit
9 Dempsey-19.)

10 BY MR. JANUSH:

11 Q. I'm going to hand you what's
12 been marked as Exhibit 19.

13 This is minutes of a
14 suspicious order monitoring workshop.

15 MR. BARKER: Did you hand me
16 two copies?

17 MR. JANUSH: Sorry, I
18 apologize. I did. Maybe you can
19 pass one down.

20 MR. BARKER: Sure. Just
21 wanted to make sure --

22 MR. JANUSH: Total mistake.

23 BY MR. JANUSH:

24 Q. And it looks at the top of

1 the workshop agenda you are listed as a
2 speaker from the 11 to 12 o'clock hour.
3 And you are listed to address current JOM
4 program and Teva or Teva benchmark.

5 Do you see that?

6 A. Yes, I do.

7 Q. In 2017 did you benchmark
8 with Teva?

9 A. In 2017, yes, we did.

10 Q. And what did you benchmark
11 on?

12 A. We reviewed how they handle
13 the authorized generic of our ADHD
14 medicine. So we -- they walked through
15 their suspicious order monitoring program
16 in regards to the handling of our
17 methylphenidate product.

18 Q. Okay. And I'm going to turn
19 your attention to the second page here.
20 And you're addressing opportunities with
21 current order monitoring program
22 discussed at December 13, 2017 workshop.

23 And by -- by the way, were
24 you the author of this document? This

1 came from your custodial file so I --

2 A. Yes.

3 Q. You are? Okay.

4 And where we see redline
5 comments, and it's DM, is that -- is that
6 your initials, Michele Dempsey?

7 A. Yes.

8 Q. Okay. So at Number 1 you
9 address algorithm. And specifically you
10 address "the current monitoring report in
11 SAP BW runs once a day, assumes all
12 orders have been placed for the day.
13 There have been instances where
14 controlled substances, Schedule III to V,
15 are placed after the report is run,
16 3:45 p.m., and there is the potential
17 that an order can be released the next
18 morning without being monitored in the
19 program.

20 "Current remediation
21 process. If order timestamp is after
22 2:30, the order is held. Tramadol,
23 Tylenol with codeine orders on business
24 manager hold until the next day, so the

1 order can run through the algorithm."

2 Did I read that right?

3 A. Yes, you did.

4 Q. Okay. And you wrote as a
5 redline edit: "Any time we need to have
6 a review done each morning by personnel
7 leads to potential of error. The current
8 remediation is not the preferred
9 long-time solution"; is that right?

10 A. Yes.

11 Q. And so by that, you were
12 addressing that the notion that your
13 orders run once a day through your SAP
14 system at 3:45 p.m. leads to a potential
15 for human error in catching something
16 that -- or in not catching an order that
17 may be placed after 3:45 p.m.; is that
18 right?

19 MR. BARKER: Object to form.

20 THE WITNESS: There is that
21 potential as it's stated.

22 BY MR. JANUSH:

23 Q. Okay. And you are also
24 addressing, at Number 2, "The current

1 monitoring report is based on three times
2 the customer's 12-month rolling weekly
3 average of shipments. The report rolling
4 average will not show slow increases in
5 order patterns or if a new customer
6 starts at higher levels verse similar
7 size customers."

8 Did I read that correctly?

9 A. Yes, you did.

10 Q. That was viewed to be a
11 weakness by you, right?

12 A. That was an opportunity for
13 an enhancement.

14 Q. Okay.

15 A. As I stated before, our
16 program was reviewed with DEA on numerous
17 occasions. They knew what our current
18 program did.

19 MR. JANUSH: Move to strike
20 as nonresponsive everything after
21 the word "enhancement."

22 BY MR. JANUSH:

23 Q. "The report does not take
24 into consideration multiple orders in one

1 month. The accumulation effect exceeding
2 the total for the month. It compares the
3 one order against the historical three
4 times 12-month week average."

5 Did you view that to be an
6 opportunity for enhancement as well?

7 A. Yes, we saw that as an
8 enhancement opportunity.

9 Q. And the current three times
10 12-month moving average was based on DEA
11 feedback for List I/precursor chemical
12 orders. We talked about that earlier,
13 right?

14 A. Yes, we did.

15 Q. "Future state monitor" --
16 "monitoring program needs to be more
17 current to industry practice."

18 Here you are acknowledging
19 that your program is not current, right?

20 MR. BARKER: Object to form.

21 THE WITNESS: Object. That
22 we have a program that DEA has
23 reviewed with us, and this is
24 after the Mallinckrodt

1 announcement came out and we were
2 using our -- this workshop as an
3 opportunity to identify future
4 enhancements.

5 BY MR. JANUSH:

6 Q. And just to wrap this up and
7 be technically correct. Earlier in the
8 day we started with a PowerPoint that you
9 drafted that showed the first quarter
10 of -- or that showed 2006, I believe Q1
11 through Q1 or Q2, 2012 and showed three
12 times or 300 percent of the average
13 annual weekly order was the mathematical
14 formula for a suspicious order.

15 Is that right?

16 A. Three times the 12-month
17 rolling, 12-month rolling average.

18 Q. Okay. And here we are, move
19 forward from 2006. Here we are 11 years
20 later in December 2017, and JOM and
21 Janssen's suspicious order monitoring
22 mathematical formula is the same, as of
23 December 13, 2017, as it was in 2006;
24 isn't that right?

1 MR. BARKER: Object to form.

2 THE WITNESS: This algorithm
3 was reviewed with DEA and DEA did
4 not provide any recommendations or
5 told us otherwise that this was
6 not acceptable. So at this time
7 that was what we used for our
8 algorithm.

9 BY MR. JANUSH:

10 Q. Okay. Now, I'd like you to
11 answer the question I asked you which is,
12 in 2006 you utilized the same
13 mathematical formula to compute a
14 suspicious order as you did as of
15 December 13, 2017; is that right?

16 A. Yes.

17 Q. And you keep referring it to
18 an algorithm. It's actually like fourth
19 grade simple math, isn't it?

20 A. I wouldn't say that.
21 Because the system has to pull all the
22 historical data and do the calculations.

23 Q. But it --

24 A. It's just a report.

1 Q. But it's just simple math.
2 It's not an algorithm. It's averaging
3 out total numbers of sales by a specific
4 product with a specific strength over a
5 year and determining if an order is three
6 times that; isn't that right?

7 A. It is identifying if there
8 is a questionable order that doesn't meet
9 the usual quantity that the customer
10 receives of that SKU.

11 Q. I'd like you to answer my
12 question.

13 Your formula is averaging
14 out the total number of historical sales
15 by a specific product SKU with a specific
16 strength that has been sold over the past
17 year, averaging those sales and
18 determining if the current order is three
19 times that average; isn't that right?

20 A. Yes. That's the -- three
21 times.

22 Q. And that isn't an algorithm,
23 is it?

24 MR. BARKER: Object to form.

1 THE WITNESS: An algorithm
2 is any calculation. And it's a
3 program in SAP.

4 BY MR. JANUSH:

5 Q. Turn to Page 36 of 6. It's
6 got a lot of redline comments on the
7 side. It's ending in Number 02987653.

8 And here I'm addressing the
9 investigation processes, at Subpart 2,
10 Paragraph 1. "When an order hits the
11 monitoring report, DEA compliance should
12 review the investigation and then make
13 the decision on whether the order should
14 ship."

15 Subpart A states, "Those
16 supporting the order, planning channel
17 ops, trade, customer service, need to
18 complete the documented investigation and
19 ensure all areas are covered in the
20 documentation."

21 Subpart B: "If channel ops
22 team knows an order is larger than
23 typical, they should communicate in
24 advance so documentation can be prepared

1 before the order is placed and run
2 through the order monitoring program."

3 Having read that, I'd like
4 to draw your attention to your comment
5 DM 7. Why don't you read that?

6 A. Sure.

7 "Currently when an atypical
8 order is identified, customer service
9 e-mails DEA compliance and that is all.
10 DEA compliance has to ask the questions,
11 collect the data, complete into a
12 document to save on the share point. We
13 are asking the owners of the information
14 to do the documentation, and then DEA
15 compliance reviews and makes final
16 decision.

17 "We'll explain more about
18 this with you later."

19 Q. Did this get implemented
20 in -- into a new SOP?

21 A. Yes, it did.

22 Q. And was that Version 10?

23 A. I'm not sure which SOP you
24 are referencing Version 10.

1 Q. If I have time later I'll --
2 I'll definitely pull it out.

3 A. Okay. Definitely. I lost
4 count of the version --

5 Q. I thought -- thought it got
6 implemented.

7 A. -- I thought it was 8, but
8 yes.

9 Q. So earlier we were talking
10 about the reports or memos that would be
11 written when a potentially suspicious
12 order is investigated. Do you -- do you
13 recall that?

14 A. Yes.

15 Q. Okay. And here you are
16 addressing that, you are asking the
17 owners of the information to do the
18 documentation. Who are the owners of the
19 information you're asking to do the
20 documentation?

21 A. The planners and channel
22 ops, as well as customer service that
23 engages with the customer.

24 Q. All right. Earlier, when

1 you testified that when you were talking
2 about customer service being involved in
3 writing the memos and that the memos
4 would be with customer service, now
5 you're talking about asking the owners of
6 the information who are planners in
7 channel ops who are different than the --
8 they're different employees than customer
9 service folks, aren't they?

10 A. They're all reporting into
11 the same organization, which is the
12 customer service deliver -- they have the
13 same leaders.

14 In the past, they did do --
15 what I was trying to say here is they did
16 eventually do all the documentation, but
17 DEA compliance had to go and tell them
18 pull the data out, let us review it.

19 So we would like to not have
20 to remind them that they could get this
21 data in advance and give it to us to
22 review. Instead of waiting for us to
23 tell them, "Did you do -- did you run
24 your reports? Did you -- did you fill

1 out -- get the questions from the
2 customer?"

3 Q. Okay.

4 A. And we changed the SOPs to
5 specifically address that that need to be
6 all done first before handing it over to
7 DEA compliance to review the entire
8 package.

9 Q. And moving on to Paragraph
10 Number 4, ordering, here you wrote, "The
11 existing suspicious order monitoring
12 program is dependent on human
13 interaction. A, every
14 shipment/order/timestamp is checked
15 manually against the SAP monitoring
16 report to ensure it was run through the
17 program (confirmed Schedule II are
18 checked, gap with Schedule III to V).

19 "B, the same restrictions on
20 order placements for Schedule IIs is not
21 used for schedule III to IV" -- "to V.
22 There is no flag in the system to prevent
23 orders from being placed throughout the
24 day for scheduled products.

1 "And C" -- which I'd like to
2 really focus with you on -- "SAP allows
3 orders to be placed anytime. There is no
4 hard stop with the monitoring report.
5 The future state program should have
6 thresholds embedded into master data such
7 that when an order is placed, the person
8 who enters it is immediately notified
9 that the order is not typical."

10 Do you see that?

11 A. Yes.

12 Q. And you wrote at Comment DM
13 11, "I think at this time the future
14 state has not been defined and approved
15 yet. IT workshop in January to define
16 whether the threshold process will work."

17 What were you referring to
18 here at Comment 11?

19 A. Oh, we were identifying if
20 this -- realtime, I enter in the order,
21 it comes up and tells me immediately,
22 versus having a report running in the
23 background at a scheduled time. We
24 didn't make that -- we were going to have

1 a future discussion on, could we do the
2 realtime. So that was saying in the
3 workshop in January, we're going to
4 define where this process will work, if
5 physically SAP could allow us to do that.

6 Q. Okay. And here, this brings
7 us full circle to what I was discussing
8 with you earlier this morning regarding
9 order monitoring. Paragraph 8, "Order
10 monitoring. Identify how chargeback/EDI
11 ValueCentric data could be routinely used
12 to identify potential suspicious trends
13 at the pharmacy patient level. Need to
14 discuss how we can use 852, 867 and
15 IntraChain (sic) data for follow-up
16 investigation on typical orders as well."

17 Did you mean IntegriChain?

18 A. Yes, I did.

19 Q. Okay. And here in that
20 bullet that I'm circling at the bottom.
21 You were writing, "IntegriChain is a
22 competitor of ValueTrak that takes all
23 the 867 field data and unblinds it so we
24 can see buying patterns. Commercial

1 excellence, Glen Moering, Cheryl, can
2 explain what data we receive and if we
3 are tracking sales."

4 Did I read that correctly?

5 A. Yes.

6 Q. This comes full circle to
7 the very type of information, and in fact
8 the third parties we were discussing
9 earlier today that your trade group was
10 utilizing to track sales, right?

11 MR. BARKER: Object to form.

12 THE WITNESS: This shows you
13 that after we learned about the
14 Mallinckrodt -- the new
15 expectation for downstream data,
16 we held a workshop to evaluate our
17 current state and determined that
18 we need to do that know your
19 customer downstream, and at that
20 time, in present at the workshop,
21 we had commercial -- if you notice
22 we had a lot of individuals from
23 the established products
24 commercial product directors, and

1 at this meeting provided that we
2 had -- they're the ones that told
3 us about IntegriChain and that we
4 could use this data.

5 So we had this
6 cross-functional workshop. We
7 reviewed the current state for
8 suspicious order monitoring,
9 including the recent issue with
10 Mallinckrodt, and this was our
11 attempt to identify future
12 enhancements to bring our program
13 up to speed.

14 And that was addressing the
15 newly discovered downstream data.

16 BY MR. JANUSH:

17 Q. You know that you didn't
18 answer my question, right?

19 MR. BARKER: Object to form.

20 THE WITNESS: Well, you were
21 trying to --

22 BY MR. JANUSH:

23 Q. Well, rather than say what I
24 was trying to do, let's actually quote

1 what I did do.

2 A. Okay.

3 Q. Question, quote: "This
4 comes full circle to the very type of
5 information, and in fact the third
6 parties that we were discussing earlier
7 today, that your trade group was
8 utilizing to track sales, right?"

9 I'm just asking if we've
10 come full circle to the very same third
11 parties, ValueTrak and IntegriChain, that
12 your trade group was bragging about using
13 in a 2012 PowerPoint earlier today?

14 MR. BARKER: Object to form.

15 THE WITNESS: This is when
16 we realized that they had this
17 downstream data, that we discussed
18 previously, that you showed me the
19 analytics. So this is when we
20 realized it was available.

21 BY MR. JANUSH:

22 Q. You realized -- your
23 testimony today, right now, is that you
24 realized in 2017 that third party vendors

1 could unblind sales data down to the
2 retail level. You personally, and your
3 group, learned that only as of 2017. Is
4 that your testimony?

5 A. That it was late in 2017
6 that I knew that there was this
7 commercial excellence group and that they
8 were buying data from IntegriChain.

9 MR. BARKER: Evan, I see you
10 going to a new document. Is this
11 a good time to break?

12 MR. JANUSH: Absolutely.

13 MR. BARKER: Whenever it's
14 convenient for you.

15 MR. JANUSH: We can break
16 right now. Let's go off the
17 record.

18 THE VIDEOGRAPHER: All
19 right. Stand by. The time is
20 4:28 p.m. We're off the record.

21 (Short break.)

22 THE VIDEOGRAPHER: Okay. We
23 are back on the record. The time
24 is 4:46 p.m.

1 (Document marked for
2 identification as Exhibit
3 Dempsey-20.)

4 BY MR. JANUSH:

5 Q. Okay. Ms. Dempsey, I'm
6 going to hand you a new exhibit. It's
7 exhibit -- Dempsey Exhibit 20.

8 MR. JANUSH: Counsel, copies
9 for you.

10 BY MR. JANUSH:

11 Q. And this exhibit is Bates
12 stamped JAN-MS-02983578, and Ms. Dempsey,
13 this is a list, kind of in a chart form,
14 of recommendations that I believe you
15 drafted. Do you see your name at the top
16 of this?

17 A. Yes.

18 THE WITNESS: Can I -- can I
19 talk to counsel?

20 BY MR. JANUSH:

21 Q. You are on the record.

22 MR. BARKER: Is it a matter
23 of privilege?

24 THE WITNESS: Yes.

1 MR. BARKER: If it's a
2 matter of privilege I'd like to go
3 off to the record -- off the
4 record and talk to her about it.

5 I'm unsure at the moment
6 what it is, but --

7 MR. JANUSH: Okay.

8 THE VIDEOGRAPHER: Off the
9 record?

10 All right. The time is
11 4:47 p.m. Off the record.

12 (Short break.)

13 THE VIDEOGRAPHER: We are
14 back on the record. The time is
15 4:49 p.m.

16 MR. BARKER: Having
17 consulted with the witness, this
18 document apparently was
19 inadvertently produced. We're
20 going to claw it back. It deals
21 with attorney work product,
22 attorney/client communications and
23 self-critical analysis, privileged
24 communications. And so we need to

1 claw this one back.

2 MR. JANUSH: So you
3 understand the rule in this
4 litigation regarding how clawbacks
5 have worked particularly when
6 noticed at depositions, right?
7 That counsel is permitted to
8 question on the clawed back
9 document. The record gets
10 preserved, and the testimony moves
11 forward subject to your clawback
12 and we litigate before Special
13 Master Cohen and/or Judge Polster,
14 the issue and propriety of your
15 clawback.

16 But that's how it's worked.
17 This has happened before with
18 respect to Cardinal. It's
19 happened in multiple significant
20 depositions. And it should happen
21 here as well.

22 You -- that's how clawback
23 works.

24 You don't just get an

1 automatic right to claw it back
2 and stop the deposition from --
3 from going forward by asserting
4 privilege.

5 We can carve out and mark
6 this portion of the record as
7 subject to your challenge and your
8 clawback. And if you win before
9 the court, the testimony that I
10 elicit will get struck from the
11 record. And I agree that it would
12 be struck if you win your proof --
13 your privilege issue.

14 My concern goes beyond the
15 late clawback and addresses the
16 notion that this is nowhere
17 identified on the Janssen
18 privilege log, that it is not
19 identified as a counsel-authored
20 document in any way. That it is
21 an e-mail forwarded by Ms. Dempsey
22 with recommendations stating here
23 you go, with a grid of
24 recommendations.

1 It's sent to a Debbie
2 Sniscak.

3 BY MR. JANUSH:

4 Q. Who is Debbie Sniscak?

5 A. She is the business
6 relationship manager in IT.

7 MR. JANUSH: Who is not a
8 lawyer. So she is communicating
9 third-party documents with a
10 nonlawyer within Janssen.

11 And so I -- I am going to
12 urge you or else I'm going to have
13 to call Special Master Cohen on
14 his cell phone right now, I'm
15 going to urge you to permit me to
16 question on your challenged
17 clawback, and preserve your
18 objection. I'm agreeing to
19 preserve it. And we can litigate
20 it before Special Master Cohen and
21 Judge Polster.

22 You should also be
23 forewarned that Judge Polster has
24 taken a very limited view as to

1 what is privileged in this case
2 concerning suspicious order
3 monitoring, including issuing a
4 ruling on November 21st in open
5 court with most defendants
6 present, including Janssen,
7 regarding suspicious order
8 monitoring and the fact that he
9 did not have a view that anything
10 related to SOM is privileged. I
11 can pull that order out, but it's
12 irrelevant because you've made an
13 objection. I responded on the
14 record. And I would like to
15 proceed subject to your right --
16 subject to your clawback argument.
17 Just as has happened in multiple
18 other depositions in this case.

19 MR. BARKER: So I'm not
20 aware that it's happened in other
21 depositions. And so at a minimum
22 what I'd like to do is go off the
23 record again, make a call. I'm
24 happy to leave the witness here.

1 It doesn't -- it's not about
2 talking to the witness. Because
3 if I can verify what you've talked
4 about, that's a lot easier than
5 trying to get the special master
6 on the phone.

7 The further understanding
8 that I have, at least with respect
9 to Judge Polster's statements
10 regarding suspicious order
11 monitoring, is that -- at least
12 Special Master Cohen has not
13 interpreted so broadly that there
14 is conceivably no privilege. It
15 was more directed at if people
16 were not disclosing any
17 information about their suspicious
18 order monitor programs, claiming
19 that the suspicious order
20 monitoring programs were entirely
21 privileged matters. And that's --

22 MR. JANUSH: I'm agreeing
23 with you on what you've just said
24 regarding Special Master Cohen's

1 view of it. And I'm asserting
2 that based on being on nearly
3 every one of the recent
4 teleconference calls with Special
5 Master Cohen, I will have no issue
6 presenting him with this document
7 and hearing what his ruling is
8 concerning this.

9 I think that it's undeniably
10 not going to be deemed privileged
11 based on -- on the face of this
12 document, and that it was
13 thereafter disclosed to a business
14 person within Janssen with nothing
15 indicating that this came from
16 counsel in any way.

17 But that said --

18 MR. BARKER: Well, you
19 didn't ask the -- the witness, and
20 I let you ask that question --

21 MR. JANUSH: Well, I --

22 MR. BARKER: I did. I
23 allowed you to ask the question.

24 MR. JANUSH: No, no, no, no.

1 You went off the record the moment
2 that I brought up the document.

3 MR. BARKER: Right, but then
4 you asked a question in the middle
5 of your speech --

6 MR. JANUSH: We're not --
7 we're not --

8 MR. BARKER: -- of the
9 witness, and I let you ask that
10 question.

11 MR. JANUSH: I didn't ask
12 the multitude of questions that I
13 would ask.

14 MR. BARKER: Okay. I
15 understand that. And you are
16 making an assumption about who
17 Ms. Sniscak is and the purpose in
18 forwarding the document.

19 But what I'd like to do is
20 go off the record --

21 MR. JANUSH: Let's call
22 Special Master Cohen.

23 MR. BARKER: Well, what I'd
24 like to do is talk to somebody

1 from my office and find out
2 whether this happened in such a
3 way.

4 I don't want to escalate
5 this and make this a dispute where
6 I'm denying that it happened. I
7 just don't want --

8 MR. JANUSH: Oh, no, I -- by
9 the way, I'm not taking the
10 position that you're denying what
11 happened. I'm addressing
12 ethically that I'm confident in
13 what I'm saying that I'm willing
14 to contact the court right now
15 rather than talk to a colleague of
16 yours that might not have been or
17 might have been at a Cardinal
18 deposition where this very issue
19 occurred. In fact, I believe more
20 than once.

21 That said --

22 MR. BARKER: Well, let's go
23 off the record and call him then.
24 If you -- if you think that that's

1 the fastest way for me to get the
2 information that I'm looking
3 for --

4 MR. JANUSH: I can't tell
5 you that I -- I have his cell on
6 my cell phone, but let's look --

7 MR. BARKER: Yeah.

8 MR. JANUSH: -- leave the --
9 the room and call.

10 MR. BARKER: Let's go off
11 the record.

12 THE VIDEOGRAPHER: Remove
13 your microphones. The time is
14 4:55 p.m. Off the record.

15 (Short break.)

16 THE VIDEOGRAPHER: We are
17 back on the record. The time is
18 5:04 p.m.

19 MR. JANUSH: To the extent
20 that I may have been overly
21 confident with respect to my
22 understanding of what occurred in
23 a prior deposition, I'm going to
24 be extra safe and agree to the

1 clawback and to not questioning
2 the witness on this document, that
3 is Bates-marked JAN-MS-02983578.

4 In accepting the clawback
5 and putting the document away, I
6 am also reserving my rights to --
7 plaintiffs' rights to challenge
8 this clawback before the Court.
9 And if plaintiffs are victorious
10 in their challenge concerning this
11 clawback, to redepose the witness
12 for the limited purpose of
13 addressing this document and the
14 contents of this document.

15 With that said, I am by no
16 means agreeing that this document
17 is, as it's been claimed, written
18 by someone other than the witness.

19 We will challenge the
20 clawback issue at a later date.
21 Feel free to make any record that
22 you need to before I move on to my
23 next document.

24 MR. BARKER: The document

1 that was marked is a two-page
2 document beginning with the Bates
3 number that you stated and going
4 on to JAN-MS-02983579.

5 Is it your understanding
6 that there are no other related
7 documents to this? In other
8 words, were there attachments that
9 you were going to roll into the
10 next exhibit? Because we may as
11 well deal with it now.

12 MR. JANUSH: There are no
13 attachments that I'm aware of.

14 MR. BARKER: Okay.

15 MR. JANUSH: But we could --
16 counsel can confirm that on the
17 system.

18 And the copies that I know
19 to exist would be on the online
20 repository that warehouses the
21 documents.

22 MR. BARKER: Okay.

23 MR. JANUSH: So I will --

24 MR. BARKER: And you have

1 hard copies that I just saw you
2 put yours away. I'm not sure
3 quite what -- oh, you're handing
4 it to me. Well, thank you. I
5 don't know what other copies you
6 have.

7 MR. JANUSH: Let me just
8 make sure that I don't have notes.

9 MR. BARKER: No, that's a --
10 and that's a fair point. You can
11 destroy it. Yeah. You don't need
12 to give it back to me, as long as
13 it gets destroyed.

14 MR. JANUSH: Ian, do you
15 have a copy to hand over?

16 MS. BOODY: I returned my
17 copy, for the record.

18 MR. BARKER: So that's all
19 the hard copies in the room.

20 MR. JANUSH: That is.

21 MR. BARKER: Okay. Next
22 exhibit. Hopefully it will be a
23 little simpler.

24 MR. JANUSH: That was marked

1 as 20.

2 MR. BARKER: That was marked
3 as 20. Yes. Do you want to
4 leave --

5 MR. JANUSH: I want to keep
6 it marked as 20 and have it
7 redacted for clawback. So that
8 it's --

9 MR. BARKER: Okay. And one
10 question for the record. I'm
11 unfamiliar with the process that
12 you're using here with the
13 electronic Elmo. Has that
14 document been made part of the
15 video record that is available to
16 you or any other party?

17 THE VIDEOGRAPHER: Yes.

18 MR. JANUSH: Okay. But you
19 have the ability to --

20 THE VIDEOGRAPHER: We can
21 take it off.

22 MR. JANUSH: -- take that
23 off.

24 THE VIDEOGRAPHER: Yes.

1 Absolutely.

2 MR. BARKER: And so that's
3 something that will happen before
4 this video gets circulated, that
5 the video operator will be taking
6 that image off the screen if it
7 appeared on the screen.

8 Yes?

9 THE VIDEOGRAPHER: Sure,
10 yes.

11 MR. BARKER: Thank you.

12 MR. JANUSH: No issues.

13 MR. BARKER: Okay. No
14 issues. Let's keep going.

15 BY MR. JANUSH:

16 Q. Would it be a true
17 statement, Ms. Dempsey, that in the
18 beginning of 2018, you, meaning JOM, did
19 not have visibility into the pharmacy
20 store level detail and wholesaler
21 distribution data which limits JOM's
22 ability to identify pharmacies generating
23 the highest number of scripts for your
24 controlled substances?

1 A. As I explained previously,
2 we had 867 data that had some blinded
3 data. But there was other data available
4 that would provide us information, the --
5 the wholesaler to the pharmacy. But not
6 all of it.

7 Q. And tell us about JOM's and
8 Janssen's ability in 2018 to have insight
9 into the population per capita to
10 associate with your historical and
11 current distribution volume, or your
12 historical and then current distribution
13 volume.

14 A. At that time, our order
15 monitoring program did not contain that
16 downstream data, and we were evaluating
17 working with outside vendors to see if
18 there was a way that we could get all
19 that information so that could be part of
20 our program.

21 Q. Okay. And one of the things
22 that you, JOM and Janssen were lacking
23 when it came to suspicious order
24 monitoring, even as of 2018, was

1 visibility into pharmacy level purchasing
2 and demand volume; isn't that right?

3 MR. BARKER: Object --
4 object to form.

5 THE WITNESS: I'm here to
6 talk about the order monitoring
7 program. And as I stated before,
8 it was constantly reviewed with
9 DEA and we had the data that DEA
10 asked for.

11 MR. JANUSH: Move to strike,
12 nonresponsive.

13 BY MR. JANUSH:

14 Q. I asked you, one of the
15 things that JOM and Janssen were lacking
16 when it came to suspicious order
17 monitoring, even as of 2018, was
18 visibility into pharmacy level purchases
19 and demand volume; isn't that right?

20 MR. BARKER: Object to form.

21 THE WITNESS: What I'm
22 saying -- what I'm objecting to is
23 that you are linking suspicious
24 order monitoring as a requirement

1 that you needed to have the
2 pharmaceutical data in the
3 statement you were saying, as part
4 of the suspicious order
5 monitoring, you needed to have the
6 pharmacy data.

7 And I'm explaining that we
8 have met with DEA, we've reviewed
9 our program, we have asked for
10 recommendations. And the last
11 time they had our SOPs was
12 December of 2017 that we provided
13 them our program. And that not
14 any of those times did they come
15 back and say well, you need to get
16 pharmaceutical data for our
17 Duragesic product.

18 BY MR. JANUSH:

19 Q. But you wanted to get
20 pharmaceutical data for your Schedule II
21 products in 2018 in order to enhance your
22 suspicious order monitoring program,
23 didn't you?

24 A. We were looking into that to

1 enhance it, because we thought that that
2 was what was the next phase of what was
3 needed.

4 Q. And one of the other things
5 that you were looking to do, was it not,
6 was to address the fact that your then
7 current suspicious order monitoring
8 program, as we've discussed a lot today,
9 only compared against a specific drug at
10 a specific strength when running the
11 mathematical formula to determine if an
12 order is suspicious. And you viewed that
13 to be an issue that should be fixed going
14 forward, right?

15 MR. BARKER: Object to form.

16 THE WITNESS: Our current
17 program was looking at Duragesic
18 SKUs, history of ordering patterns
19 with our customers.

20 DEA regulations say you have
21 to have a system in place that
22 monitors orders, and it doesn't
23 say you need to have pharmacy data
24 downstream. We were monitoring

1 orders to our customer.

2 MR. JANUSH: Move to strike,
3 nonresponsive.

4 I'm not speaking about
5 downstream. I asked you a
6 different question.

7 BY MR. JANUSH:

8 Q. I asked, and one of the
9 other things that you were looking to do,
10 was it not, was to address the fact that
11 your then current suspicious order
12 monitoring program, as we've discussed a
13 lot today, only compared a specific drug
14 at a specific strength when running the
15 mathematical formula to determine if a
16 order is suspicious. And you viewed that
17 to be a problem, right?

18 MR. BARKER: Object to form.

19 THE WITNESS: Not a problem.

20 But an enhancement that we should
21 be considering in how to include
22 more information in our program.

23 BY MR. JANUSH:

24 Q. In other words, from 2006 to

1 at least the beginning of 2018, Janssen
2 didn't aggregate all of the strengths of
3 Duragesic, as an example, into its
4 mathematical formula when determining if
5 a particular Duragesic order for a
6 specific strength was atypical or
7 suspicious; is that right?

8 MR. BARKER: Object to form.

9 THE WITNESS: Our order
10 monitoring program looked at the
11 Duragesic product SKU. There was
12 no requirement that we did a sum
13 of all of the SKUs.

14 BY MR. JANUSH:

15 Q. In other words, you didn't
16 look at the customer's aggregate purchase
17 history of Schedule II products. You
18 only looked at a specific strength of a
19 specific product, right?

20 MR. BARKER: Object to form.

21 THE WITNESS: As I
22 mentioned, on a quarterly basis we
23 look at the total volume of
24 controlled substances compared to

1 the total volume. And I think, I
2 believe you reviewed the trend in
3 graphs so you can see in some --
4 in some of the major wholesalers,
5 our controlled substance orders
6 were less than 9 percent, or
7 actually it dropped to 3 percent,
8 of the total volume of products
9 that we shipped to the wholesaler.

10 MR. JANUSH: Move to strike
11 as nonresponsive.

12 MR. BARKER: Object to the
13 motion to strike.

14 THE WITNESS: But we were
15 monitoring the total amount of
16 controlled substances going to the
17 customers.

18 MR. JANUSH: Move to strike
19 as continued to be nonresponsive.

20 BY MR. JANUSH:

21 Q. Earlier we discussed the
22 December 2017 suspicious order monitoring
23 workshop. Do you remember that?

24 A. Yes.

1 Q. And I showed you a document
2 concerning the minutes of that workshop,
3 right?

4 A. Yes.

5 Q. And some of the things that
6 you considered were how to improve your
7 then existing suspicious order monitoring
8 platform, right?

9 A. We did discuss enhancements
10 to our existing program.

11 Q. Okay.

12 (Document marked for
13 identification as Exhibit
14 Dempsey-21.)

15 BY MR. JANUSH:

16 Q. I've marked as Exhibit 21 an
17 e-mail between you and Christopher
18 Villani. Who is Christopher Villani?

19 A. He is in marketing.

20 Q. He's in marketing?

21 A. Janssen sales and marketing.
22 Commercial.

23 Q. Do you know what his
24 specific title is?

1 A. I don't recall.

2 Q. Okay. And you were
3 forwarding him an e-mail between you and
4 Andres Lopez, Frank Mashett. I'm -- I'm
5 not going to pronounce the next name
6 correctly. Why don't you help me there?

7 A. Nguyen Tran.

8 Q. Nguyen Tran?

9 A. Mm-hmm.

10 Q. And John Leahy and Scott
11 Trembly, Tracy Guldán, Thomas Stukane and
12 Brian Strehllke who were on the cc line.

13 Are these all Janssen
14 employees that -- that you were writing
15 to at this moment?

16 A. Yes.

17 Q. And you were forwarding an
18 e-mail from Sue Sopko of IntegriChain; is
19 that right?

20 A. Yes.

21 Q. And what you were forwarding
22 was an e-mail that also attached a
23 statement of work that I don't have
24 attached to this e-mail. And I don't

1 know if it was produced. I can't
2 represent whether it was or wasn't. If
3 it wasn't we'll address that later as
4 well.

5 You were -- you were
6 receiving an attached statement of work
7 to support Janssen's efforts to identify
8 and take action on any potential abuse of
9 your controlled substance product
10 distribution.

11 Do you see that?

12 A. Yes, I do.

13 Q. Do you agree with that
14 language?

15 A. This was to -- to present
16 out the downstream data. Yes.

17 Q. Do you agree with the
18 language that -- that you were seeking
19 IntegriChain's statement of work to
20 support Janssen's efforts to identify and
21 take action on any potential abuse of
22 your controlled substance product
23 distribution?

24 MR. BARKER: Object to form.

1 THE WITNESS: Yes.

2 BY MR. JANUSH:

3 Q. Okay. And Sue notes,
4 "Reasons you are not able to effectively
5 monitor and detect potential abuse of
6 your controlled substance distribution.

7 "You currently do not have
8 visibility into the pharmacy, store level
9 detail, and wholesaler distribution data
10 which limits your ability to identify the
11 pharmacies generating the highest number
12 of scripts for your controlled
13 substances."

14 Did I read that correctly?

15 A. Yes, you did.

16 Q. Did you agree with that
17 statement?

18 A. As I had mentioned before,
19 our data was blinded. So we did not have
20 the visibility to all of the pharmacy
21 state level detail.

22 Q. And it goes on, Sue goes on
23 to say, "Additionally, you currently do
24 not have insight into the population per

1 capita to associate with your historical
2 and current distribution volume."

3 And she continues,
4 "Capabilities you said you need to more
5 effectively monitor and detect suspicious
6 order activity in your distribution
7 channel to keep up with the DEA
8 regulatory compliance and internal
9 reporting requirements are:

10 "Visibility into
11 pharmacy-level purchasing and demand
12 volume."

13 Did you agree with that?

14 MR. BARKER: Object to form.

15 THE WITNESS: That is what
16 she was quoting on, yes.

17 BY MR. JANUSH:

18 Q. "Visibility into
19 pharmacy-level purchasing to determine if
20 duplicate orders to multiple wholesalers
21 are occurring."

22 Did you agree with that
23 statement by Sue?

24 MR. BARKER: Object to form.

1 THE WITNESS: This was all
2 part of her statement of work.
3 This is what she was communicating
4 to us that they could provide us.
5 So we did not say this is exactly
6 what we need. They were coming to
7 us to say that this is what they
8 can give us, visibility of the
9 pharmacy level as well as
10 visibility into the purchasing
11 determinative of duplicate orders.

12 So I did not say I wanted
13 this. But she was telling us what
14 we need.

15 BY MR. JANUSH:

16 Q. Okay. So go up --

17 A. Based on what they --

18 Q. Go up a few --

19 A. -- can provide.

20 Q. Go up a few sentences. I'm
21 not trying to cut you off. I'm just
22 trying to speed this along. Go up a few
23 sentences to capabilities. I'm going to
24 underline it for you. "Capabilities you

1 said you need to more effectively monitor
2 and detect suspicious order activity in
3 your distribution channel to keep up with
4 the DEA regulatory compliance and
5 internal reporting requirements are."

6 Did you not say that you
7 need these things? Did she make this up?

8 A. Not in the exact wording.
9 She took what we were saying in our -- in
10 our introduction meeting and put it into
11 what data they have that they can provide
12 us.

13 Q. Okay.

14 A. So we were asking for
15 downstream understanding of where our
16 product is going, the pharmacy, and
17 that's what she came back and provided
18 us.

19 Q. "Understand the population
20 per capita for your highest geographic
21 distribution areas."

22 Was this something that you
23 expressed you would like data on?

24 A. We said we wanted regional

1 analysis. And that's how she interpreted
2 the regional analysis.

3 Q. Okay. "Understand the
4 market behavior associated with similar
5 and competitive products to provide a
6 baseline to determine atypical behavior."

7 Did you say that you wanted
8 that capability?

9 A. In -- not exactly in those
10 words, but we did want to know how our
11 compounds compared to competitors.

12 Q. "Understand the purchasing
13 behavior of your wholesalers to ensure
14 compliance."

15 Did you want that capability
16 to effectively monitor and detect
17 suspicious orders?

18 MR. BARKER: Object to form.

19 THE WITNESS: As a -- we
20 were confirming that our
21 wholesalers were doing their due
22 diligence in their suspicious
23 order monitoring by ensuring that
24 there was not any questionable

1 quantities going to downstream.

2 BY MR. JANUSH:

3 Q. So my question is, did you
4 want the data that would provide you with
5 the capability to understand the
6 purchasing behavior of your wholesalers
7 to ensure compliance?

8 MR. BARKER: Object to form.

9 THE WITNESS: With respect
10 to wholesalers, yes.

11 BY MR. JANUSH:

12 Q. "The ability to leverage
13 historical data and trends to develop
14 ordering thresholds to monitor and
15 potentially hold suspicious orders."

16 Did you want that ability?

17 MR. BARKER: Object to form.

18 THE WITNESS: We -- we asked
19 if there was information that we
20 could evaluate as part of our
21 order threshold calculations.

22 BY MR. JANUSH:

23 Q. I'm not going to cover every
24 sentence in the e-mail. I'm going to

1 turn you back to the first page. When
2 you wrote to all these Johnson & Johnson
3 folks, okay, did you ever express in the
4 body of your e-mail that you disagreed
5 with any of her statements?

6 A. Let me read it.

7 Once again, it contained
8 information. But I was providing this
9 information to the leadership team that
10 participated in the workshop as a
11 potential solution to know our -- to know
12 our downstream data.

13 MR. BARKER: Actually, as I
14 look at this e-mail that you were
15 just asking about, the February
16 14th one, we need to go off the
17 record, and I can ask the witness
18 or you can ask the witness whether
19 this relates to the same subject
20 matter as the exhibit that we just
21 clawed back.

22 THE WITNESS: It does.

23 MR. BARKER: Okay. But --

24 MR. JANUSH: While we're on

1 the record.

2 BY MR. JANUSH:

3 Q. The -- is it your testimony
4 that the -- the prior exhibit that was
5 clawed back at Exhibit 20 contained
6 information that was conveyed to you by
7 IntegriChain?

8 MR. BARKER: Objection. No.

9 Look --

10 MR. JANUSH: I'm
11 trying to -- you're saying the
12 same --

13 MR. BARKER: Evan, just so
14 that you're clear, what I'm saying
15 is in the middle of this e-mail,
16 it looks like there is privileged
17 information that is attorney work
18 product and self-critical analysis
19 privilege, privileged, and that it
20 should have been redacted.

21 And it's not the e-mail from
22 the vendor to her which you've
23 been talking about. It's what you
24 just moved on to, as I sit here

1 and I read it.

2 It's the February 14th,
3 2018, e-mail from Ms. Dempsey to
4 several people dated 2/01. That
5 is what has the privileged
6 information in it. So if this
7 document had been properly
8 produced, it -- this would have
9 been redacted and you would have
10 had the information at the bottom
11 that you were just questioning the
12 witness about. But I see this
13 information, and I can see it's
14 the same as the document we just
15 clawed back.

16 MR. JANUSH: Actually, and I
17 don't have the document committed
18 to memory that you clawed back,
19 but from my -- from my memory, it
20 actually is not the same
21 information. It may have
22 overlapping information.

23 MR. BARKER: It's not
24 literally the same. But it falls

1 within the same realm of
2 privileged information in that
3 section of the document.

4 MR. JANUSH: And just so
5 that I understand what the
6 privilege is that's being
7 asserted, can you address this on
8 the record so that I understand,
9 because all I see is that Sue
10 Sopko, a vendor, wrote to Michele
11 Dempsey and provided an attached
12 statement of work and addressed
13 the issues concerning the reasons
14 that Janssen or JOM was not able
15 to effectively monitor suspicious
16 order monitoring, at least in the
17 words of the consultant.

18 And that the middle e-mail
19 that you're referring to on Page 1
20 is Michele Dempsey, our witness,
21 the deponent, addressing to a
22 bunch of J&J folks what was
23 conveyed during a -- December 2017
24 workshop minutes, of which I've

1 already addressed and the subject
2 matter which I've already
3 addressed, earlier in this
4 deposition.

5 THE WITNESS: But the next
6 sentence is not the content from
7 the workshop.

8 MR. BARKER: Yeah, so hang
9 on a second, because you asked --
10 you asked for the position. So
11 I'll tell you what the positions.

12 MR. JANUSH: Yeah.

13 MR. BARKER: You are
14 misreading and misunderstanding
15 what the consultant means in that
16 middle e-mail. You are assuming
17 that it is the IntegriChain person
18 below, which is it is not. And so
19 there's a wholly separate issue
20 that's going on in the content of
21 that middle e-mail.

22 I do not dispute that that
23 e-mail that you just talked to her
24 about and the scope of work, not

1 privileged. That portion of the
2 document, I had no issue with.
3 It's when you turned to this and I
4 read this that I have an issue
5 because of what's being
6 communicated there.

7 Since I'm clawing it back.
8 We'll give you a redacted version
9 of this document. But I'm clawing
10 it back. I'm not going to debate
11 this any further. The grounds are
12 attorney work product,
13 attorney/client privilege and
14 self-critical analysis privilege.

15 MR. JANUSH: Okay. So that
16 we can get this matter addressed
17 expeditiously through the court,
18 and since it's only been two
19 documents that have been clawed
20 back during this deposition, will
21 you agree to provide the basic
22 privilege log-type information
23 very soon within a reasonable time
24 period so that the to, the from,

1 the who the consultant is, et
2 cetera, so that we can address
3 this and address this and tee it
4 up before Special Master Cohen?

5 MR. BARKER: And I'm not
6 sure what -- our processes on
7 that. But yes, I think that is a
8 fair ask. And I will -- I will
9 commit that we will get that as
10 fast as our processes allow.

11 So if we can have those
12 copies back, and we'll get you a
13 redacted copy.

14 MR. JANUSH: This copy
15 actually should go to the court
16 reporter and remained marked as
17 clawback, because it's part of the
18 trial transcript and video exhibit
19 with the writings.

20 MR. BARKER: Here's a
21 suggestion for you on that. If
22 you pull off that top page, and
23 then we can put a sticker on that
24 page that you were using, then at

1 least -- because again, I am
2 not --

3 MR. JANUSH: Let the record
4 reflect that I pulled off the top
5 page and handed it back to
6 counsel.

7 Here's the other top page.

8 BY MR. JANUSH:

9 Q. There came a point in time,
10 Ms. Dempsey, in May of 2018 where Janssen
11 and JOM were considering a revision to
12 the proposed current mathematical formula
13 or the then-current mathematical formula
14 of three times the average annual weekly
15 order and considering a different
16 algorithm; is that right?

17 A. Yes.

18 Q. And one of the algorithms
19 that was being considered to change to
20 was the two-Sigma rule combined with 867
21 data feeds that you would get from
22 IntegriChain. Do you recall that
23 discussion?

24 A. Not specifically.

1 Q. Has Janssen since -- has
2 Janssen ever modified its suspicious
3 order monitoring mathematical computation
4 through the present date since 2006?

5 Bless you.

6 A. The current order monitoring
7 program continues to exist as it is from
8 2006.

9 Q. Janssen never moved to a
10 two-Sigma or a two-standard deviation
11 rule, did it?

12 A. No. We are currently
13 working with an outside vendor Analysis
14 Group who is going to be, currently in
15 the upcoming months, going to provide us
16 with -- actually this week, they are
17 going to review some of the statistical
18 analysis that they are going to recommend
19 in regards to monitoring our customers.

20 Q. Okay. Has Analysis Group
21 provided you with a proposed scope of
22 work?

23 MR. BARKER: Wait a minute.

24 MR. JANUSH: These are --

1 this is all discoverable. This is
2 all part of -- you can challenge
3 the -- the concept of whether it
4 gets produced, but --

5 MR. BARKER: True.

6 MR. JANUSH: -- the
7 knowledge of whether a scope of
8 work has been provided is
9 something that's gone before the
10 court.

11 MR. BARKER: I'm only going
12 to object to the extent you're
13 calling for any advice that was
14 actually provided.

15 If you want foundational
16 information that meetings have
17 happened, that sort of stuff, I
18 agree, you are entitled --

19 MR. JANUSH: And -- and
20 whether a written scope of work
21 has been conveyed. That's all.

22 MR. BARKER: Yes, you can --
23 you can get into that.

24 MR. JANUSH: I'm not going

1 to get into it with you on that.

2 MR. BARKER: But -- but what
3 I -- all I wanted -- my objection
4 is privilege, and I'm just
5 instructing the witness not to
6 disclose the content of any
7 communications or recommendations.

8 And so with respect to the
9 foundational matters, go ahead and
10 ask your question.

11 MR. JANUSH: I asked it.

12 You know it.

13 BY MR. JANUSH:

14 Q. You can answer it.

15 A. Yes, we got a statement of
16 work.

17 Q. Okay. Did you receive more
18 than one statement of work from Analysis
19 Group?

20 A. We received two.

21 Q. Okay. On or about what
22 dates did you receive such statement of
23 work?

24 A. I don't recall the dates.

1 Q. Have you entered into a
2 contract yet with Analysis Group to
3 modify or create a new suspicious order
4 monitoring program for Janssen?

5 MR. BARKER: Object to form.

6 THE WITNESS: We are working
7 with them to enhance our current
8 order monitoring program.

9 BY MR. JANUSH:

10 Q. You can answer. I'm not --
11 I'm not trying to be your attorney. But
12 you are allowed to answer whether you've
13 entered into a contract with Analysis
14 Group.

15 A. Yes.

16 Q. You have?

17 A. Yes.

18 Q. Okay. Do you know which
19 person or persons on behalf of Janssen
20 executed that contract with Analysis
21 Group?

22 A. JOM.

23 Q. Do you know what person
24 within JOM would have negotiated and

1 executed the contract?

2 MR. BARKER: Object to form.

3 THE WITNESS: It may have
4 been Andres Lopez.

5 BY MR. JANUSH:

6 Q. And remind me of Andres
7 Lopez's title?

8 A. He is director customer
9 experience -- customer service.

10 Q. Is he an attorney?

11 A. No.

12 (Document marked for
13 identification as Exhibit
14 Dempsey-22.)

15 BY MR. JANUSH:

16 Q. I'm going to hand you what I
17 marked as Exhibit 22. This will be my
18 last exhibit.

19 And I'm going to turn your
20 attention to Vishal Varma's e-mail on
21 May 16, 2018, middle of the page, at
22 JAN-MS-02969720.

23 Who is Vishal Varma?

24 A. He is Johnson & Johnson's IT

1 digital strategy I believe.

2 Q. And you -- you forwarded
3 this e-mail to a Soledad Cepeda stating
4 that "Soledad, we are in the process of
5 enhancing our suspicious order monitoring
6 program for our existing products,
7 Concerta, Duragesic, tramadol, and
8 esketamine. There is a group addressing
9 the data analytics where our products" --
10 "where are products are going." I think
11 you meant our products are going.

12 "Would you like to
13 participate in the project? Michele."

14 Who is Soledad Cepeda?

15 A. The next page. She is
16 epidemiology.

17 Q. Okay. And in the middle of
18 the page where Vishal Varma is writing to
19 you, she is writing: "Hi, Michele.
20 Absolutely appreciate you passing along
21 all background documentation which always
22 helps us understand the state of the art,
23 and hence calibrate our anomaly detection
24 algorithms.

1 "On blinded data, we are
2 pursuing a couple of possible pathways.
3 We have started discussions with Daniel
4 Kinney from commercial data governance.
5 He is ex-IntegriChain alum and will help
6 us to have a dialogue with their senior
7 level. See if we can facilitate flow of
8 unblinded data. He is going to get
9 IntegriChain to visit us."

10 I'm going to stop there.

11 A. Mm-hmm.

12 Q. Is that how you started to
13 work with IntegriChain?

14 A. No.

15 Q. How did -- how did you start
16 to come to know IntegriChain and get
17 their proposal?

18 A. I learned in the previous
19 fall, from the Concerta commercial team,
20 that they were -- they were getting
21 IntegriChain data on our ADHD medicine.

22 So Cheryl, I forget her last
23 name, did set up an introduction with
24 IntegriChain previous to this.

1 Q. Okay. And below is an
2 e-mail from February 28, 2018, in this
3 string from Sue Sopko of IntegriChain to
4 you following up on the presentation deck
5 that Shivani had presented to you and
6 Janssen on Monday -- I guess that would
7 be Monday, February 26th.

8 Who is Shivani? Is she an
9 employee at IntegriChain?

10 A. Yes.

11 Q. Okay. And did Janssen ever
12 enter into a scope of work or a contract
13 with IntegriChain?

14 A. Yes.

15 Q. Okay. And is Janssen still
16 working with IntegriChain now to assist
17 with providing unblinded data for
18 Janssen's SOM program?

19 A. Yes.

20 Q. How far along is that
21 process?

22 A. That statement of work was
23 signed before Christmas.

24 Q. Okay.

1 A. So.

2 Q. So did the work -- did the
3 work commence yet?

4 A. I'm not quite sure how much
5 is done. But it was kicked off.

6 MR. JANUSH: Okay. Okay.
7 At this point I have no further
8 questions, subject to my
9 Reservation of Rights if we should
10 win the clawback issues.

11 And subject to one other
12 issue that I need to note for the
13 record.

14 During this deposition I
15 learned that over 1,000 documents
16 were produced over the weekend,
17 many of which concern suspicious
18 order monitoring. I had thought
19 that we were pushing the
20 suspicious order monitoring
21 deposition in order to accommodate
22 additional document production
23 from Janssen. I don't have
24 personal knowledge of that

1 production as I've been in this
2 room all day; however, I'm going
3 to look into it and I want to
4 reserve my rights to reopen this
5 deposition, if it is, in fact, the
6 case that documents that concern
7 the topics Ms. Dempsey has
8 testified on today were produced
9 belatedly over the weekend,
10 particularly over a holiday
11 weekend.

12 That's all that I have to
13 say on that topic.

14 MR. BARKER: Okay. My
15 understanding is that document
16 productions have been ongoing in
17 this case. And I don't know what
18 was produced over the weekend.
19 And I don't know what the base of
20 information is that you're working
21 from there. So I don't know how
22 to respond to that here.

23 It's been a long day. The
24 witness appears tired. But I'll

1 talk to her. And if she's
2 prepared to go for another hour,
3 hour and a half tonight, then we
4 can -- we can do my redirect.

5 Otherwise I propose that we
6 just start in the morning and we
7 knock it out in the morning.

8 But let me talk to her first
9 and find out how she is feeling.

10 MR. JANUSH: Okay. And just
11 so you understand where I'm coming
12 from, you know, I want to make
13 sure that my objection regarding
14 the recent document production is
15 clear.

16 The parties have been
17 serving -- the defendants have
18 been serving what is called
19 substantial completion charts by
20 topic, and suspicious order
21 monitoring is a topic within the
22 substantial completion charts.
23 And for quite sometime Janssen has
24 represented that its production

1 was substantially complete.

2 I've also had significant
3 correspondence with Amy Lucas of
4 your firm as you know, because
5 you've been copied on that
6 correspondence, regarding my
7 serious concerns about late
8 document production concerning
9 suspicious order monitoring,
10 anti-diversion, et cetera.

11 So I'll let the records of
12 my e-mails speak for themselves,
13 and certainly the issue of the
14 substantial compliance charts.

15 But again, I'm only saying
16 this to preserve the record. I'm
17 not representing that I have yet
18 have firsthand knowledge of what
19 was produced because I have not
20 been on the site to personally
21 review the documents.

22 When I do, and if there's an
23 issue, I'll raise it at the
24 appropriate time. I just wanted

1 to preserve the record.

2 MR. BARKER: And let me --
3 when we take the break, I also
4 want to do some digging. I want
5 to find out what's going on with
6 that production in particular,
7 because if there is an issue, it
8 might make sense, rather than come
9 back today, tomorrow for another
10 couple hours, to defer that and we
11 can -- maybe we can make an
12 arrangement. I'm not agreeing
13 that --

14 MR. JANUSH: I understand --

15 MR. BARKER: You want more
16 than seven hours, I think you're
17 entitled to it. I'm saying during
18 this next break, find out some
19 additional information so that you
20 and I can have a discussion off
21 the record and figure out what
22 makes the most sense in this case.

23 MR. JANUSH: Thank you for
24 your courtesy.

1 THE VIDEOGRAPHER: All
2 right. The time is 5:45 p.m. Off
3 the record.

4 (Short break.)

5 THE VIDEOGRAPHER: The time
6 is 6:29 p.m. Back on the record.

7 MR. BARKER: After
8 conferring with counsel during the
9 break, I think we've mutually
10 agreed that it makes the most
11 sense to sort out any issues with
12 respect to the document
13 production.

14 We believe that it was made
15 on Thursday or Friday. Counsel
16 believes that it may not have been
17 made until Sunday. Neither one of
18 us are representing that that is a
19 firm understanding as to when the
20 documents were produced.

21 But in any event, it looks
22 like we're going to have to come
23 back on another day. So we're --
24 we're going to hold the deposition

1 open for now. And we're going to
2 have a discussion to figure out
3 when would be the next most
4 convenient date to get back
5 together, that allows counsel to
6 review the documents that he says
7 were produced over the weekend,
8 that we believe were produced last
9 week.

10 And we are also going to try
11 to sort out the issues with the
12 documents that were clawed back
13 today at the deposition. And
14 we're going to have a further
15 discussion about that to see if we
16 can resolve issues on that.

17 And failing that, if we can
18 figure out a way to resolve the
19 clawback issues, such that the
20 deposition can go forward and
21 counsel is either going to be
22 permitted to ask questions about
23 those documents or not.

24 MR. JANUSH: And this is

1 Evan Janush for plaintiffs. I
2 want to add to this record that
3 plaintiffs seek information,
4 additional information concerning
5 the circumstances in which the
6 clawed-back documents were
7 created, vendor information, who
8 retained the vendor, who shared
9 the documents, who -- who received
10 the documents, et cetera.

11 And I understand that
12 Mr. Barker is not -- is not
13 prepared to address that right
14 now, I'm okay with that.

15 But we seek that information
16 in order to be able to put a
17 cogent argument before the court
18 as to why the documents may not be
19 properly the subject of a
20 clawback.

21 In addition, concerning the
22 subject of the recently produced
23 document production by Janssen,
24 whether the documents were

1 produced Thursday, Friday or
2 Sunday, we can address at another
3 time.

4 I just want the record to be
5 clear that there has been a
6 long-standing dispute concerning
7 the suspicious order monitoring
8 production in this case, and only
9 after a challenge by me were
10 hundreds of documents produced
11 days before the originally
12 scheduled deposition of Ms.
13 Dempsey's -- for Ms. Dempsey,
14 resulting in the -- the
15 accommodation by Mr. Barker to
16 reschedule the deposition without
17 argument.

18 And with the recent
19 production that occurred, whether
20 it's Thursday, Friday or Sunday,
21 as we believe occurred, there was
22 no notification by counsel for
23 Janssen that any documents, albeit
24 potentially more than a thousand,

1 concerning suspicious order
2 monitoring were being produced in
3 advance of this deposition.

4 So without that heads-up, I
5 had no idea to focus in on a
6 recent document production to
7 prepare for this deposition. And
8 if it proves to be true that the
9 documents concern suspicious order
10 monitoring, we are going to seek a
11 reasonable accommodation for
12 additional time and a respectful
13 accommodation.

14 MR. BARKER: And without
15 agreeing with the factual
16 predicates asserted for that
17 request, we've agreed that we will
18 discuss whether a reasonable
19 accommodation can be made, and
20 that it would be appropriately
21 sized to whatever issue there may
22 be, if any, regarding production
23 of suspicious order monitoring
24 documents.

1 MR. JANUSH: Agreed.

2 MR. BARKER: So with that, I
3 think that we're prepared to have
4 the court reporter prepare this
5 transcript, even though the
6 deposition will continue.

7 We asked the videographer
8 before going back on the record
9 what the total record time today
10 is, and it was 6 hours 35 minutes.
11 And the state of play right now is
12 counsel has passed the witness to
13 me, and that we will take up the
14 direct exam of Ms. Dempsey at a
15 later date.

16 MR. JANUSH: I would only --
17 I would only state that if it is
18 the case that, either through
19 agreement or through the Court,
20 that the deposition -- additional
21 time would be afforded to
22 plaintiffs by virtue of the
23 recently produced documents, that
24 my passing of the witness would be

1 rendered moot, and I would still
2 be in my direct on the original
3 documents that should have been
4 produced earlier and wouldn't be
5 redirecting the witness with these
6 recently produced documents.

7 MR. BARKER: And we can have
8 a further discussion off the
9 record about such issues. The
10 amount of documentation relating
11 to suspicious order monitoring
12 going back to at least 2014 is a
13 massive material. And as it has
14 been located, we have been
15 producing it. Our production has
16 not been staged in any way in an
17 attempt to prejudice plaintiffs or
18 to game the system.

19 There's a large amount of
20 information. It is in a lot of
21 different places. The locations
22 have changed over time, as the
23 witness has told you today, and
24 we're doing our best to gather it

1 all and produce it as fast as
2 possible.

3 MR. JANUSH: And to be
4 clear, not to belabor this, but
5 I've not cast any aspersions or
6 addressed an attempt to prejudice
7 me. I would only say that it
8 would have been good to have the
9 heads-up in advance, and we
10 probably could have had a second
11 reasonable discussion about moving
12 the deposition, if it was required
13 based on the volume of recently
14 produced documents.

15 And I wasn't afforded that
16 opportunity. So that's why I
17 addressed that. It may be
18 premature to confirm that I've
19 passed the witness.

20 MR. BARKER: As the record
21 reflects, we now have that
22 opportunity.

23 THE VIDEOGRAPHER: Off the
24 record?

1 MR. BARKER: Off the record,
2 yes.

3 THE VIDEOGRAPHER: Okay.
4 This marks the end of today's
5 deposition. The time is 6:36 p.m.
6 Off the record.

7 (Excused.)

8 (Adjourned at approximately
9 6:36 p.m.)

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1
2 CERTIFICATE
3
4

5 I HEREBY CERTIFY that the
6 witness was duly sworn by me and that the
7 deposition is a true record of the
8 testimony given by the witness.

9 It was requested before
10 completion of the deposition that the
11 witness, MICHELE R. DEMPSEY, have the
12 opportunity to read and sign the
13 deposition transcript.

14
15 _____
16 MICHELLE L. GRAY,
17 A Registered Professional
18 Reporter, Certified Shorthand
19 Reporter, Certified Realtime
20 Reporter and Notary Public
21 Dated: January 25, 2019
22
23
24

25 (The foregoing certification
26 of this transcript does not apply to any
27 reproduction of the same by any means,
28 unless under the direct control and/or
29 supervision of the certifying reporter.)
30
31
32

1 INSTRUCTIONS TO WITNESS

2
3 Please read your deposition
4 over carefully and make any necessary
5 corrections. You should state the reason
6 in the appropriate space on the errata
7 sheet for any corrections that are made.

8 After doing so, please sign
9 the errata sheet and date it.

10 You are signing same subject
11 to the changes you have noted on the
12 errata sheet, which will be attached to
13 your deposition.

14 It is imperative that you
15 return the original errata sheet to the
16 deposing attorney within thirty (30) days
17 of receipt of the deposition transcript
18 by you. If you fail to do so, the
19 deposition transcript may be deemed to be
20 accurate and may be used in court.

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4 PAGE LINE CHANGE

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2 ACKNOWLEDGMENT OF DEPONENT
3

4 I, _____, do
5 hereby certify that I have read the
6 foregoing pages, 1 - 411, and that the
7 same is a correct transcription of the
8 answers given by me to the questions
9 therein propounded, except for the
10 corrections or changes in form or
11 substance, if any, noted in the attached
12 Errata Sheet.
13
14
15

16 _____
MICHELE R. DEMPSEY

DATE

17
18
19 Subscribed and sworn
to before me this

20 _____ day of _____, 20____.

21 My commission expires: _____
22 _____

23 Notary Public
24

	LAWYER'S NOTES		
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